

EXHIBIT H

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

- - - - - x
IN RE: VALSARTAN, LOSARTAN, AND : MDL NO. 2875
IRBESARTAN PRODUCTS LIABILITY :
LITIGATION, :
:
THIS DOCUMENT RELATES TO: :
Duffy, et al. v. Solco Healthcare :
U.S., L.L.C., et al., :
Case No. 1:18-cv-15076-RBK-JS :
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VOLUME II

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Veritext Virtual Zoom Videotaped
deposition of MAHYAR ETMINAN, taken on Wednesday,
August 25, 2021, held in Vancouver, City of British
Columbia, Canada, commencing at 8:32 a.m., before
Jamie I. Moskowitz, a Certified Court Reporter and
Certified Livenote Reporter.

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(All appearances via Zoom)

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1 REQUEST PAGE

2 INSTRUCTIONS NOT TO ANSWER:

3 Page Line

4 None

5 REQUEST FOR PRODUCTION OF DOCUMENTS:

6 Page Line Description

7 None

8 STIPULATIONS:

9 Page Line

10 None

11 QUESTIONS MARKED:

12 Page Line

13 None

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1 THE VIDEOGRAPHER: The time is now
2 8:32. This is a continuation of
3 Mahyar Etminan's deposition. We are back on
4 the record.

5 EXAMINATION BY MR. GALLAGHER:

6 Q Good morning, Dr. Etminan.

7 A Good morning.

8 Q At this time, I don't -- at this time
9 I don't have further questions for you. Some of the
10 other defense counsel do, so I'm going to turn it
11 over to counsel for Mylan.

12 EXAMINATION BY MR. TRISCHLER:

13 Q Good morning, Doctor.

14 A Good morning.

15 Q I'll just start by introducing myself
16 to you. My name's Clem Trischler. I represent the
17 Mylan defendants in this litigation. I'll be asking
18 you some questions following up on Mr. Gallagher.

19 If you can -- if you have any trouble
20 hearing me, please let me know so I can rephrase or
21 repeat the question. Okay?

22 A Okay.

23 Q Let me start by asking you this
24 relatively simple and straightforward question,
25 Doctor. Would you agree with me that NDMA and NDEA

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1 are ubiquitous?

2 MR. NIGH: Form objection.

3 THE WITNESS: Yes, generally speaking.

4 BY MR. TRISCHLER:

5 Q Those compounds are found virtually
6 everywhere, true?

7 MR. NIGH: Form objection.

8 THE WITNESS: Generally speaking, yes.

9 BY MR. TRISCHLER:

10 Q NDMA and NDEA are found in the air we
11 breathe, in the water we drink and in the food we
12 eat, correct?

13 A Yes.

14 Q In fact, I think you wrote in your
15 report that NDMA and NDEA are found in pesticides,
16 hair dye, air, water and food. That's what you
17 wrote I think on Page 7 of your report, right?

18 A Yes.

19 Q So it's a known fact that each and
20 every one of us are exposed to nitrosamines such as
21 NDMA and NDEA on a daily basis, true?

22 A Yes.

23 Q And as part of your work in this case,
24 have you attempted to quantify the baseline level of
25 exposure to NDEA that the average American receives

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1 on a daily basis?

2 A No, not personally.

3 Q Have you done any original research in
4 your career that's been designed to determine or
5 calculate the baseline daily exposure to NDEA?

6 A No.

7 Q Are you aware of the fact that there
8 are studies that have been published in the
9 peer-reviewed literature that suggest that dietary
10 intake of NDEA and NDMA can be as high as 2,000
11 nanograms per day for the average American?

12 MR. NIGH: Form objection.

13 THE WITNESS: That -- I mean, that's
14 possible. I don't remember of a specific
15 paper, but that's possible.

16 BY MR. TRISCHLER:

17 Q Okay. And are you aware of the same
18 studies suggesting that smokers have a daily intake
19 of NDEA and NDMA that can be as high as 20,000 --
20 25,000 nanograms per day?

21 A I'm not aware of studies, but it's
22 possible that's the case.

23 MR. NIGH: Form objection to that
24 question.

25

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1 BY MR. TRISCHLER:

2 Q Assuming there are studies that
3 suggest daily intake of nitrosamines for smokers can
4 be as high as 20,000 to 25,000 nanograms per day, do
5 you have any scientific basis to dispute that fact?

6 MR. NIGH: Form objection.

7 THE WITNESS: Well, I mean I have
8 to -- I have to read the scientific paper and
9 then see exactly how that number was derived.
10 So I think you're asking me a very general
11 question.

12 BY MR. TRISCHLER:

13 Q Well, I don't know whether it's
14 general or specific. I'm just asking you a
15 question, and the question is this: As you sit here
16 today providing testimony under oath, are you aware
17 of any evidence to suggest that daily intake of
18 nitrosamines for smokers is something other than 20
19 to 25,000 nanograms per day on average?

20 MR. NIGH: Form objection.

21 THE WITNESS: I -- I don't -- I didn't
22 look at nitrosamine exposure among smokers, so,
23 again, this is -- this is not an area that I
24 specifically looked at. I know generally
25 speaking, smokers could have a higher

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1 concentration of NDMA than nonsmokers.

2 BY MR. TRISCHLER:

3 Q And I think what you said as part of
4 your research in this case and part of your work in
5 this case, you did not do any analysis to determine
6 baseline exposures for either NDEA or NDMA, right?

7 MR. NIGH: Form objection.

8 THE WITNESS: Yes.

9 BY MR. TRISCHLER:

10 Q Would you agree that if an individual
11 consumes alcohol, his or her daily exposure to NDEA
12 and NDMA would be expected to increase?

13 A Than a nonalcoholic, yes.

14 Q Well, not just a known alcoholic, but
15 anyone that consumes alcoholic. I like a beer or
16 two from time to time, and I don't think I'm an
17 alcoholic. But when I consume alcohol, research
18 suggests that my daily intake of nitrosamines is
19 going to go up. Wouldn't you agree?

20 A It's -- yeah, it's going to go -- it's
21 going to be higher than, you know, when you were not
22 taking alcohol or compared to somebody who's not
23 taking alcohol.

24 Q Sure, so -- so we can agree that
25 there's a baseline of exogenous exposure to NDEA and

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1 NDMA that all of us experience, right?

2 A Yes.

3 Q All of us have a lifetime of exposures
4 to NDMA and NDEA, right?

5 A Yes.

6 Q Every plaintiff in this litigation has
7 been exposed to NDMA and NDEA throughout their
8 lifetimes just like you and I have, right?

9 A Yes.

10 Q In this case, though, you've done
11 nothing to independently assess, evaluate or
12 quantify what that baseline exposure is, right?

13 MR. NIGH: Form objection.

14 THE WITNESS: You're talking about me
15 undertaking a study, looking at your question.

16 That was not what I did or I was asked to do.

17 BY MR. TRISCHLER:

18 Q I understand. That's what I'm just
19 trying to clarify. There were things were you asked
20 to do and things you were not.

21 And one of the things you have not
22 done is to quantify a baseline exposure for NDEA and
23 NDMA for any plaintiff in this litigation or any
24 average person in the community, right?

25 MR. NIGH: Form objection.

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1 THE WITNESS: Yes.

2 BY MR. TRISCHLER:

3 Q Nothing in your report that's been
4 filed with the court in this case quantifies
5 baseline NDEA or NDMA exposures, agreed?

6 MR. NIGH: Object to form.

7 THE WITNESS: Yes.

8 BY MR. TRISCHLER:

9 Q And at the outset of yesterday when
10 you were being asked questions by Mr. Gallagher,
11 what I recall you stating is that what you were
12 retained to do was to review the literature and
13 provide an answer to the question of whether NDMA,
14 regardless of route of administration, could
15 plausibly cause cancer in humans. That was the
16 question you were asked, and you -- and you
17 undertook a literature review to try to answer that
18 question, correct?

19 A Yes.

20 Q And while that was the question you
21 were asked to evaluate, I think, as we have just
22 established, there were other questions concerning
23 NDMA and NDEA that you never examined, right?

24 A Well, what do you mean by "other
25 questions"?

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1 Q Well, for instance, we talked about
2 the fact that you never researched the amounts of
3 NDMA that the average American adult consumes on a
4 daily basis, right?

5 A I do have in my report a citation of
6 general range of exposure of NDMA in -- you know, in
7 the American diet. And I agree with you that, you
8 know, generally, they are all exposed to NDMA, you
9 know, from the environment or from air or what have
10 you.

11 Q Right. And I think you agreed with me
12 that daily exposure is on the order of
13 2,000 nanograms per day. But my question was that
14 was not the -- determining that average baseline
15 exposure from dietary intake was not the question
16 that you were asked to answer?

17 MR. NIGH: Hold on. Hold on. Object
18 to form, mischaracterizes his testimony. Never
19 was there an agreement that the average
20 baseline is 2,000 nanograms of NDMA.

21 You can answer.

22 MR. TRISCHLER: I don't think speaking
23 objections are permitted, Daniel, so please
24 don't do it.

25 MR. NIGH: Well, you can't

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1 mischaracterize testimony.

2 MR. TRISCHLER: Well, I think you can
3 object to form, but let's not -- let's not
4 start testifying, please.

5 MR. NIGH: Okay. Form objection.

6 THE WITNESS: Yes.

7 BY MR. TRISCHLER:

8 Q And you never researched the amount of
9 NDEA that the average American consumes on a daily
10 basis, right?

11 A Yes.

12 Q You have not reviewed the cases of any
13 plaintiff in this litigation to calculate their
14 cumulative -- cumulative lifetime exposure to NDMA
15 or NDEA prior to the time they consumed any
16 valsartan-containing medication, right?

17 A Correct.

18 Q Have you ever -- we have been talking
19 about exogenous exposure, but have you ever
20 independently researched endogenous formation of
21 nitrosamines where the extent of endogenous
22 formation that occurs prior to the time you were
23 retained in this case?

24 A No.

25 Q And in connection with your work in

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1 this case, have you ever done any research to try
2 and answer the question of the extent of endogenous
3 formation of nitrosamines that occurs in the human
4 body?

5 A No. I mean, that -- that is not my
6 field of expertise.

7 Q Understood.

8 Are you aware of any research
9 suggesting that all of us endogenously form
10 nitrosamines in our body at levels even higher than
11 what we consume exogenously?

12 A I know that there is potential for
13 endogenous formation of NDMA in -- in the human
14 body.

15 Q Right. And in reading some of the
16 studies that you cite in your report, and that you
17 were kind enough to discuss with us yesterday, some
18 of those studies suggest that the level of
19 nitrosamines that form endogenously are far greater
20 than what we consume on a daily basis, right?

21 MR. NIGH: Form objection.

22 THE WITNESS: Yes.

23 BY MR. TRISCHLER:

24 Q In fact, I think one of the papers
25 that was cited in your report was a paper that was

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1 published by a gentleman named Jakszyn as the lead
2 author -- lead author, excuse me. Jakszyn is
3 spelled J-a-k-s-z-y-n, I believe. Do you recall
4 that paper?

5 A Yes.

6 Q I think it was entitled "Endogenous
7 Versus Exogenous Exposure to Nitroso Compounds" and
8 was marked as Exhibit 12, yesterday. Do you
9 remember that?

10 A Right.

11 Q And according to that paper by
12 Jakszyn, we're exposed to over 93,000 nanograms of
13 nitrosamines every single day. Do you remember
14 that?

15 MR. NIGH: Form objection.

16 THE WITNESS: I do remember that.

17 BY MR. NIGH:

18 Q And as part of your work in this case,
19 you have not done any independent research studies
20 or testing to -- to suggest or establish that the
21 estimates of total nitrosamine exposure as predicted
22 by Jakszyn were incorrect, fair to say?

23 A Yes.

24 Q And I trust you'd agree with me that
25 if you want to evaluate the impact of nitrosamines

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1 in valsartan-containing medications, what we need to
2 consider is the extent to which individual
3 consumption of NDMA and NDEA increase due to the
4 presence of those compounds in the drugs, right?

5 MR. NIGH: Form objection.

6 THE WITNESS: I mean, if you want to
7 do a perfect study, yes, that's -- that's what
8 needs to be done.

9 BY MR. TRISCHLER:

10 Q And in assessing carcinogenicity of
11 any compound, you agree that dose and duration of
12 exposure are always important, right?

13 A Generally speaking, yes.

14 Q Right. Well, in fact, yesterday, we
15 discussed the Pottegard and Gomm studies. Do you
16 remember that?

17 A Yes.

18 Q And one of the things I remember from
19 your testimony yesterday was that you were critical
20 of those studies because the amount of NDMA exposure
21 was not specified in the controls. Do you recall
22 telling us that?

23 A Yes.

24 Q And you told us that, you know, for
25 that -- in that study, you would have liked to have

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1 seen the controls broken down by high exposure,
2 medium exposure and low exposure. Do you remember
3 telling us that?

4 A Yes.

5 Q And the inference from that is that
6 you wanted them broken down that way because dose
7 and duration are undoubtedly important and
8 undoubtedly contribute to carcinogenicity, right?

9 A Yes.

10 MR. NIGH: Form objection.

11 BY MR. TRISCHLER:

12 Q And in this case, you've been very
13 clear and very honest and open in telling us that
14 you have not done any work to -- since you have not
15 done any work to establish baseline exposures,
16 right?

17 MR. NIGH: Form objection.

18 THE WITNESS: Yes, I think I have
19 answered that already.

20 BY MR. TRISCHLER:

21 Q Right. And since you have not done
22 any work to establish baselines, you can't tell us
23 the extent to which any plaintiff's daily intake of
24 NDMA or NDEA increased due to the use of
25 valsartan-containing medications, right?

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1 A Correct.

2 Q So if we -- I told you at the outset I
3 introduced myself, my client is Mylan. If we use
4 Mylan is an example. You reference my client I
5 think only in one place in that -- in your --

6 THE COURT REPORTER: I'm sorry. You
7 cut out.

8 BY MR. TRISCHLER:

9 Q I said you reference Mylan only in one
10 place in your entire report. Would you agree?

11 A I believe it's the -- the part where I
12 show the ranges of -- of NDMA in the product.

13 Q Agreed.

14 You -- you -- you provided us with a
15 40-page report, and the only place where you ever
16 mention my client is in a footnote on Page 8,
17 correct?

18 A Yes. I wasn't asked to write reports
19 for different manufacturers.

20 Q I understand. But in that footnote,
21 you suggest that NDEA concentrations in some of
22 Mylan's products were found to range from .01 parts
23 per million to 1.57 parts per million. Do you
24 remember writing that?

25 A Yes.

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1 Q And the -- as part of your work in
2 this case, did you -- did you calculate the mean
3 parts per million that was observed in Mylan's
4 product?

5 A I remember I may have calculated
6 either the mean or the -- or the higher range of the
7 PPM.

8 Q Well, if you calculated a mean, what
9 did you calculate?

10 A I don't remember off the top of my
11 head. But I mean, if I can just do a quick
12 calculation if you tell me what the -- if I can --
13 I'm just looking at my report.

14 Q Well, to calculate the mean, you'd
15 need to know a lot more than just what the lower
16 bound and what the upper bound of the range was,
17 right?

18 A Yes.

19 Q Right. And the only information you
20 have in your report is the low -- low range being
21 .01 parts per million, and the high being 1.57 parts
22 per million -- per million. So how would you
23 calculate a mean? But you can't calculate a mean
24 based on that. You'd need other data and other
25 information.

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1 A Yeah, I probably -- I probably just --

2 MR. NIGH: Hold on. Hold on. Let me

3 object to the form first. Form objection.

4 You can answer, Doctor.

5 THE WITNESS: I probably only looked

6 at the higher -- higher end of the 1.57.

7 BY MR. TRISCHLER:

8 Q So -- so your best recollection,
9 sitting here today, is you never calculated a mean
10 concentration of NDEA in the Mylan product, right?

11 A Right.

12 Q Well, I'll represent to you that
13 the -- for purposes of my questions that the mean
14 concentration for -- in Mylan's product is observed
15 to be 0.047 parts per million, okay?

16 A Okay.

17 Q And if we assume the -- did you --
18 were you made aware of the fact that the largest
19 concentration in which valsartan-containing
20 medications or the largest dose in which
21 valsartan-containing medications were made available
22 in the United States was 320 milligrams per day?

23 A Yes.

24 Q And so if the mean is .047 parts per
25 million, and we assume the largest dose of

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1 320 milligrams, that results in a mean exposure of
2 150 nanograms, correct?

3 A Correct.

4 Q So going back to Jakszyn's data in
5 Exhibit 12 that you -- in his paper that you
6 included with your report, if his estimate of
7 nitrosamine exposure of 93,000 nanograms per day is
8 accurate, in 150 nanogram --

9 THE COURT REPORTER: I'm sorry. You
10 broke up. You broke up.

11 MR. TRISCHLER: I'll start over.

12 BY MR. TRISCHLER:

13 Q If we assume the data from Jakszyn's
14 paper is accurate, then adding a 150-nanogram
15 exposure to a daily nitrosamine exposure of 93,000
16 nanograms is miniscule, correct?

17 MR. NIGH: Object to form. Object to
18 form.

19 THE WITNESS: Well, again, we --
20 that's -- the Jakszyn study is one study. It
21 has some limitations. Back to your -- back to
22 your point, the 150, I believe the -- the Mylan
23 nanogram per -- the mean Mylan nanogram per day
24 of 150 is -- one has to look at this as a
25 cumulative exposure. So patients would be

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1 taking this over extended period of time. 150
2 is still higher than the -- the recommended or
3 the allowable daily dose by the FDA.

4 And you are sort of assuming that only
5 the patient who's taking the 150-nanogram Mylan
6 dose has that endogenous exposure -- sort of
7 exposure to endogenous nitrosamines as well.
8 In other words, you know, in the population, as
9 we spoke earlier, we are all exposed to
10 nitrosamines. So population-wise, there is no
11 reason to believe that the people who are not
12 taking that extra dose of Mylan also do not
13 have endogenous exposure to NDMA.

14 What I'm trying to say is that
15 endogenous exposure in the population is
16 probably very similar, at least in the American
17 population, based on the diet. And if a
18 patient is taking an extra dose of 150
19 nanograms per day of Mylan or any other
20 exposures, an extra dose added to that baseline
21 dose, which again is higher than the
22 recommended daily dose by the FDA, cumulatively
23 over a long period of time, it is possible that
24 that dose could potentially increase the risk
25 of cancer.

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1 MR. TRISCHLER: Objection, move to
2 strike as nonresponsive.

3 BY MR. TRISCHLER:

4 Q Let's see if we can try this again,
5 Doctor.

6 A 150-nanogram exposure is miniscule
7 compared to a 93,000-nanogram exposure, right?

8 MR. NIGH: Object to form.

9 THE WITNESS: Yes.

10 BY MR. TRISCHLER:

11 Q It's .01 percent of the total
12 exposure, simple math, right?

13 MR. NIGH: Object to form.

14 THE WITNESS: Yes, but you are -- you
15 are -- you're assuming that the -- that there
16 is one patient taking -- exposed to endogenous
17 X amount -- I don't know if the Jakszyn study
18 is -- is the true endogenous value. But let's
19 say there is an X amount of endogenous NDMA in
20 one person. That person is being -- is adding
21 to that, cumulatively, an extra dose. You're
22 assuming that the other people who are not
23 taking that extra dose do not have endogenous
24 exposure, and only that patient has endogenous
25 plus exogenous exposure.

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1 What I'm trying to say that in a
2 population, as we discussed, where diets are
3 pretty stable, and this is in the U.S., for the
4 most part, most people will have that baseline
5 endogenous exposure. So the person who's
6 taking the exogenous NDMA in valsartan, you'll
7 have -- you'll have an added extra risk if
8 you're taking it cumulatively every day.

9 So that -- that's what I was trying to
10 explain to you.

11 BY MR. TRISCHLER:

12 Q I think I understand, Doctor. I'm not
13 making the assumption that you believe I am. I
14 agree with you 100 percent, that every one of us has
15 exogenous and endogenous exposures to nitrosamines.
16 And if Jakszyn is correct, that that exposure is on
17 the order of 93,000 nanograms per day.

18 And so my -- so the issue in this
19 case, then, is does an exposure of an extra
20 150-nanograms representing a .01 percent increase in
21 that exposure level result in a substantial --
22 statistically significant increased risk of cancer.
23 That's the question I want to answer.

24 And what I'm asking hearing from you
25 is that's not a question -- I haven't asked the

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1 question. That's not a question you ever answered
2 in this case. You certainly don't answer it in your
3 report, right?

4 MR. NIGH: Hold on. Object to the
5 colloquy, argumentative.

6 You can answer.

7 THE WITNESS: So, again, as I
8 mentioned yesterday, I'd love to answer that
9 question. But the -- the type of question
10 you're asking, data for that question, good
11 data, is not available. What I was asked to do
12 is to answer the question as a general
13 causation question, does exposure to NDMA over
14 time increase the risk of cancer. So that's
15 what I -- that's what my systematic review
16 addressed.

17 BY MR. TRISCHLER:

18 Q Understood.

19 A I did not -- I did not address mostly
20 because I -- you know, I did search for the data.
21 But that specific question that you're asking -- and
22 it's quite more of an individual -- you know,
23 individual causation question rather than a general
24 causation question. So I did not answer that, the
25 type of question you're asking.

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1 Q Well, I agree with a lot of what you
2 said. I disagree that it's not a general causation
3 question.

4 But I think what we can really agree
5 on is your statement that good data does not exist
6 to answer the question of whether an incremental
7 increase in nitrosamine exposures above the baseline
8 that we all experience will lead to a statistically
9 significant increased risk of cancer. It's not a
10 question that you answered, and the data is not
11 there to answer it. That's what you just told us
12 under oath, right?

13 MR. NIGH: Object to form.

14 You can answer.

15 THE WITNESS: Again, I -- in my
16 report, I -- I was asked to answer whether
17 there is general causation with exposure to
18 NDMA over time. That's what I answered in my
19 report.

20 BY MR. TRISCHLER:

21 Q And you did not answer the question of
22 whether an incremental increase over some period
23 of -- over some period less than lifetime would lead
24 to a statistically significant increased risk of
25 cancer because the data is not there to answer that

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1 question, agreed?

2 MR. NIGH: Object to the form.

3 You can answer.

4 THE WITNESS: I answered the question
5 that NDMA exposure over time increases the risk
6 of cancer. I did not answer the question of
7 incremental increase, and I really don't
8 understand what you mean by "statistically
9 significant."

10 But I did not answer the question
11 whether incremental increase of any specific
12 doses of NDMA increased the risk of cancer. I
13 answered a more general question of exposure,
14 exposure over time versus cancer risk.

15 BY MR. TRISCHLER:

16 Q In your review of the scientific
17 literature, did you find a single cohort or case
18 control study that reported that a 1 to 2-percent
19 increase in daily NDMA exposure would lead to a
20 statistically significant increased risk of
21 esophageal cancer?

22 MR. NIGH: Object to form.

23 THE WITNESS: Can you repeat the
24 question, please?

25 BY MR. TRISCHLER:

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1 Q In your review of the scientific
2 literature, did you find a single cohort or case
3 control study that reported that a 1 to 2-percent
4 increase in daily NDMA exposure would lead to a
5 statistically significant increased risk of
6 esophageal cancer?

7 MR. NIGH: Object to form.

8 THE WITNESS: I don't know if the
9 study looked at 1 to 2-percent increase, but
10 there are -- the dietary studies that I
11 included have looked at sort of a dose response
12 exposure of NDMA per day, looking at high
13 versus low doses with respect to cancer.

14 BY MR. TRISCHLER:

15 Q Can you cite me any study, as you sit
16 here today, where the authors looked at incremental
17 increases in nitrosamine exposure and concluded that
18 a 1 to 2-percent increase in NDMA or NDEA intake
19 would lead to an increased risk of cancer?

20 A Can you clarify --

21 MR. NIGH: Hold on. Hold on. Object
22 to the form.

23 You can answer.

24 THE WITNESS: Can you clarify what you
25 mean by "incremental increase"?

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1 BY MR. TRISCHLER:

2 Q What I'm -- what we've been talking
3 about, Doctor, that we all have a baseline of -- of
4 exposure that we have been receiving on a daily
5 basis. Let's assume that that baseline exposure is
6 2,000-nanograms. If we were exposed to
7 2,000-nanograms for the first 40 years of our life,
8 and then in year 41, we begin to -- that exposure
9 increases to 2,100 nanograms per day, what I want to
10 know is: Are there any studies to suggest that an
11 incremental increase in daily nitrosamine exposure
12 is expected to lead to an increased risk of cancer?

13 MR. NIGH: Hold on. Hold on. Hold
14 on. Hold on. Object to the form.

15 THE WITNESS: What I think you're --
16 you're referring to is whether -- whether there
17 is a dose response increase with NDMA exposure
18 and cancer so that the more NDMA you take over
19 a period, your risk of cancer is higher.

20 So again, some of the dietary studies
21 that I've discussed have looked at subjects who
22 have taken the highest cumulative dose of NDMA
23 in their diet and compared them to the -- to
24 the lowest, considering that all of those --
25 all of that population is also exposed to some

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1 level of endogenous NDMA through their diet.

2 They have looked at exogenous NDMA
3 using dietary measures and looked at that dose
4 response. So I think, again, your -- I think
5 your question is whether there's a dose
6 response relation. And I have shown in my
7 report that some of these dietary studies have
8 shown a dose response.

9 BY MR. TRISCHLER:

10 Q That's not -- that wasn't my question,
11 but let me -- so let me try to ask it again.

12 Name me a study that's in your report
13 or that you uncovered in your research that
14 establishes that there is an increased risk of
15 cancer if my nitrosamine intake is increased by
16 5 percent for a period of five years.

17 MR. NIGH: Sorry. Was that the end of
18 the question?

19 MR. TRISCHLER: Yes.

20 MR. NIGH: Okay. Object to form.

21 THE WITNESS: Again, I think -- I
22 think you're asking -- I think your question is
23 asking the same concept of a dose response in a
24 different fashion.

25 And so again, if -- the studies may

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1 not have looked at nitrosamines in the way
2 you're asking the question. But they have
3 looked at those response. You're -- you're
4 basically saying does somebody who has an
5 increase in 1 to 2 percent over five years,
6 does that person have a higher risk of cancer,
7 and I think what -- and I think what you mean,
8 and correct me if I'm wrong, is compared to
9 somebody who doesn't have that 1 to 2 percent
10 increase. That -- that is a dose response
11 question, and I'm -- and that has been looked
12 at in the dietary studies, not -- not exactly
13 the way you have put it. But they have looked
14 at cumulative dosing.

15 BY MR. TRISCHLER:

16 Q Well, I'm -- well, the way you phrased
17 the question is the way I'm looking for you to
18 answer it, Doctor.

19 And -- and so my question is, tell me
20 the -- name me the dietary study where it says that
21 a slight, short duration increase in nitrosamine
22 exposure is gonna increase your risk for developing
23 cancer. I can -- I read your papers, the papers you
24 sent. I can't find it, so tell me where it is.

25 MR. NIGH: Object to form. This is

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1 getting argumentative, lots of colloquy. It's
2 inappropriate. It's not a question.

3 MR. TRISCHLER: It's a question. It
4 might not be a good one, Dan, but it's a
5 question.

6 MR. NIGH: But the -- "I've read your
7 report. I can't find out where it is." You
8 know, that's not a question. That's
9 argumentative. It's inappropriate.

10 THE WITNESS: Again, the -- the -- the
11 dose response analysis done in the dietary
12 studies look at or present a dose response
13 relation. They have not looked at it the way
14 you have portrayed your question or the way you
15 want the dose response to be looked at. But
16 they have addressed -- I still think that your
17 question -- your question is a dose response
18 question. And they have addressed dose
19 response in the way that all dietary studies
20 address them, high dose versus low dose. What
21 is the risk? Is there a difference in risk?

22 BY MR. TRISCHLER:

23 Q And what you're saying -- what you're
24 suggesting with your answer is the same thing I
25 think we already talked about, and that is that dose

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1 and duration do matter, correct?

2 A Yes.

3 Q Right. And so what I'm trying to
4 define is when does the dose and duration exposure
5 to nitrosamines lead to an increased risk of cancer?
6 Where do we draw the line? You have cited in your
7 report -- you have got 71 references listed in this
8 report, correct?

9 A Yes.

10 Q Tell me by number which one of those
11 71 references that I can go to that is going to
12 suggest that if I increase my daily nitrosamine
13 exposure by 5 percent or less for some period of
14 time, that I'm -- I'm at an increased risk for
15 cancer? Does that -- does that data exist anywhere?

16 MR. NIGH: Objection.

17 THE WITNESS: Again, the -- the way --
18 the question that you're asking me, that --
19 that type of analysis, I -- I did not find.
20 But I did include, as you mentioned, dietary
21 studies of the dose response analysis.

22 BY MR. TRISCHLER:

23 Q We talked about the fact that all of
24 us are exposed to NDMA and NDEA on a regular basis,
25 true?

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1 A Correct.

2 Q But we can agree that while all of us
3 are exposed to NDMA and NDEA every day, not all of
4 us are going to develop cancer, correct?

5 A Yes.

6 Q So there's obviously a threshold dose
7 or a threshold exposure at which NDMA and NDEA will
8 not cause harm, agreed?

9 MR. NIGH: Object to form.

10 THE WITNESS: I -- I don't know. I
11 don't know the answer to that question.

12 BY MR. TRISCHLER:

13 Q You have never calculated a threshold
14 dose for NDEA, have you?

15 A Well, you're -- your question is not
16 about the threshold dose on NDMA -- NDEA. I believe
17 your question is whether there is a threshold dose
18 in causing cancer, and so that requires another
19 study. It's not as simple as just calculating
20 threshold dose.

21 BY MR. TRISCHLER:

22 Q Well, I'm just asking you if you've
23 ever done it.

24 A No, because that requires, again, a
25 very large sophisticated study, and I -- I have not

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1 done it. And I was not -- that's not what I was
2 asked to do.

3 Q Are you familiar with the concept of
4 permissible daily exposure?

5 A Yes.

6 Q Is it true that permissible daily
7 exposure is defined as a dose that's unlikely to
8 cause an adverse effect if the individual is exposed
9 at or below that dose for a lifetime?

10 A I believe that's what it stands for.

11 Q Okay. Have you ever calculated a
12 permissible daily exposure for any nitrosamine?

13 A No, because I relied on the
14 epidemiologic studies that I looked at. I mean, the
15 permissible daily exposure mostly comes from animal
16 data.

17 Q I'm just asking if you have ever
18 calculated a PDE for any nitrosamine?

19 A No. I appreciate that, but I just
20 need to be able to explain myself. So, no, I have
21 not.

22 Q Do you agree there is one though,
23 right?

24 A There is one, for example, the FDA has
25 one, yes.

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1 Q Well, the FDA has an acceptable intake
2 level that it's established for nitrosamine levels
3 in drug products, but that's not a PDE, is it?

4 MR. NIGH: Object to form.

5 THE WITNESS: It may not be. I'll
6 have to -- I'd have to check.

7 BY MR. TRISCHLER:

8 Q Well, just think about it. We've
9 already -- we've already talked about and
10 established that nitrosamines are ubiquitous and
11 we're exposed to them from lots of sources, not just
12 drugs, right?

13 A Yes.

14 Q Right. So there's a -- there's a
15 permissible daily exposure for all nitrosamines
16 including NDMA and NDEA. You've -- but you've not
17 determined what they are, correct?

18 MR. NIGH: Object to form.

19 THE WITNESS: I don't know -- I mean,
20 I could have during my research, but it doesn't
21 ring a bell right now.

22 BY MR. TRISCHLER:

23 Q And you don't recall seeing any data
24 suggesting a PDE for NDEA or NDMA, right?

25 A Correct.

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1 Q Are you aware of any research that's
2 been published in the peer-reviewed literature
3 suggesting that a short-term increase in NDEA or
4 NDMA exposure above the PDE will lead to an
5 increased risk of cancer in humans?

6 MR. NIGH: Object to form.

7 THE WITNESS: No.

8 BY MR. TRISCHLER:

9 Q So if I could summarize what I
10 understand your work in this case to be, Doctor, is
11 that -- your focus was on addressing the general
12 question of whether the literature supports a
13 plausible causal connection between NDMA and cancer
14 in humans, right?

15 MR. NIGH: Object to form.

16 THE WITNESS: Yes.

17 BY MR. TRISCHLER:

18 Q I didn't hear your answer because of
19 the objection.

20 A Yes.

21 Q And your -- your research was not
22 focused on dose or duration or on examining the
23 impact of incremental increases in daily exposures,
24 right?

25 MR. NIGH: Object to form.

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1 THE WITNESS: Yes.

2 BY MR. TRISCHLER:

3 Q And now I want to ask you some
4 questions specifically about NDEA. Before you were
5 retained in this case, had you ever done any
6 original clinical research on the carcinogenicity of
7 NDEA?

8 A No.

9 Q For that matter, before you were
10 retained by the plaintiffs' lawyers in this case,
11 had you ever done any original clinical research on
12 the carcinogenicity of NDMA?

13 A No.

14 Q Had you ever published any
15 peer-reviewed studies assessing or evaluating the
16 carcinogenicity of NDEA in humans?

17 A No.

18 Q Had you ever published any
19 peer-reviewed studies assessing or evaluating the
20 carcinogenicity of NDMA in humans?

21 A No.

22 Q Had you ever done any animal studies
23 or participated in any animal studies looking at the
24 carcinogenicity of any nitrosamine?

25 A No. I'm not a basic scientist, so no.

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1 Q Okay. Had you ever participated in
2 any epidemiological studies involving NDEA?

3 A No.

4 Q Had you ever participated in any
5 animal study -- or excuse me. Have you ever
6 participated in any epidemiological studies
7 involving NDMA?

8 A No.

9 Q Prior to the time the plaintiffs'
10 lawyers knocked on your door to ask you to work on
11 this case, had you ever done any work in your
12 professional career with nitrosamines?

13 A No.

14 Q So is it fair to say that in your
15 career as a -- in the fields of pharmacology and
16 epidemiology, that you never researched, studied or
17 investigated the possible association of
18 nitrosamines and cancers before you were retained in
19 this case?

20 A I have done studies in the past on
21 carcinogens and cancer, but not specifically on
22 nitrosamines.

23 Q Right. And so since you had no
24 specific background in studying, researching or
25 investigating nitrosamines, the only basis for your

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1 opinion as to whether NDMA or NDEA can cause cancer
2 in humans is the literature that -- review that you
3 did in connection with this case, right?

4 A Yes.

5 MR. NIGH: Object to form.

6 BY MR. TRISCHLER:

7 Q And in the -- with that literature
8 review, I want to ask you specifically about NDEA.

9 Did you identify in your literature
10 review any observational study in the literature
11 that found a statistically significant association
12 between NDEA and breast cancer?

13 A Specifically on breast cancer?

14 Q Yes, NDEA and breast cancer.

15 A No.

16 Q In your research for purposes of this
17 case, did you -- can you identify any observational
18 study that you found in the literature that reported
19 a statistically significant association between NDEA
20 and esophageal cancer?

21 A No.

22 Q In connection with your work in this
23 case, can you identify for me any observational
24 study in the literature that found a statistical --
25 statistically significant association between NDEA

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1 and stomach cancer?

2 A No.

3 Q In connection with your work in this
4 case, can you identify any observational study that
5 you found in the literature that found a
6 statistically significant association between NDEA
7 and colorectal cancer?

8 A No.

9 Q In connection with your work in this
10 case, can you identify any observational study in
11 the literature that found a statistically
12 significant association between NDEA and liver
13 cancer?

14 A No.

15 Q In connection with your work in this
16 case, can you identify any observational study in
17 the literature that found a statistically
18 significant association between NDEA and lung
19 cancer?

20 A No.

21 Q In connection with your work in this
22 case, can you identify any observational study that
23 found a statistically significant association
24 between NDEA and bladder cancer?

25 A No.

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1 Q In connection with your work in this
2 case, can you identify any observational study
3 published in the literature that found a
4 statistically significant association between NDEA
5 and prostate cancer?

6 A No.

7 Q In connection with your work in this
8 case, can you identify any observational study
9 reported in the literature with a statistically
10 significant association between NDEA and blood
11 cancers?

12 A No.

13 Q In connection with your work in this
14 case, can you identify any observational studies
15 published in the literature that found a
16 statistically significant association between NDEA
17 and pancreatic cancer?

18 A I identified one study by Zheng that
19 looked at NDEA and found an increase in risk.

20 Q And that -- that paper was -- the lead
21 author was Zheng, Z-h-e-n-g, correct?

22 A That's right.

23 Q And that was published in 2018 in a
24 publication called "Carcinogenesis"?

25 A Yes.

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1 Q And would you agree with me that even
2 while finding an association between pancreatic
3 cancer and NDEA, the authors of the Zheng paper were
4 careful to note that their observations were
5 preliminary?

6 A That's what they may have stated in
7 their paper, yes.

8 Q And isn't it true that the authors of
9 that paper were careful to note that the findings
10 and this reported association between NDEA and
11 pancreatic cancer was merely preliminary?

12 A If that's what they said in their
13 paper, then that's what they said, but -- I mean,
14 that's what --

15 Q Well, you read -- you read it. Do you
16 recall?

17 A I have read a lot of these papers. I
18 can read it now. I don't recall that statement,
19 but --

20 Q Isn't it true that the authors of the
21 Zheng paper noted that their findings were
22 preliminary and needed to be confirmed in a large
23 prospective cohort study with consideration of
24 sufficient time between diet assessment and disease
25 diagnosis?

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1 MR. NIGH: Object to form.

2 THE WITNESS: That is -- they are sort
3 of portraying a perfect scenario. I'm not sure
4 if -- and they call this preliminary. I'm not
5 sure if there will ever be a large prospective
6 study looking at this question again, but
7 that's what they state.

8 BY MR. TRISCHLER:

9 Q Well, that was going to be my next
10 question. Do you -- are you aware of the large
11 prospective cohort study that Zheng and his
12 colleagues recommended to be done, whether it was
13 ever done?

14 MR. NIGH: Object to form.

15 THE WITNESS: I'm not aware.

16 BY MR. TRISCHLER:

17 Q We talked about my client,
18 Mylan Pharmaceuticals, a bit and how you mentioned
19 them in that footnote on Page 8.

20 Can we agree that nowhere in your
21 40-page report that you filed in this case did you
22 ever conclude that an increase in NDEA intake in the
23 amounts contained in Mylan's valsartan-containing
24 medication to cause cancer in humans?

25 MR. NIGH: Can you repeat that? You

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1 broke up. You broke up at the end.

2 MR. TRISCHLER: Sure.

3 MR. NIGH: Thank you.

4 BY MR. NIGH:

5 Q Can we agree that nowhere in your
6 report you ever conclude that an increase in NDEA
7 intake in the amounts contained in Mylan's
8 valsartan-containing medications was sufficient to
9 cause cancer in humans?

10 A Yes.

11 Q And you -- and in your work in this
12 case, you have not found a single study in the
13 peer-reviewed literature that would support a
14 statistically significant increased risk of any
15 cancer from a short-term duration nitrosamine intake
16 increase of 150 nanograms per day, right?

17 A You mean a specific study that -- that
18 looks at that specific dosage and cancer?

19 Q Yes.

20 A No.

21 Q The -- the -- are you familiar with
22 the concept of latency periods in cancer?

23 A Yes.

24 Q Do you know what the average latency
25 period is for esophageal cancer?

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1 A Specifically for esophageal cancer,
2 no.

3 Q Do you know the average latency period
4 for stomach cancer?

5 A No.

6 MR. NIGH: Object to form.

7 BY MR. TRISCHLER:

8 Q Do you know the average latency period
9 for colorectal cancer?

10 MR. NIGH: Object to form.

11 THE WITNESS: The latency period for
12 cancer in general is usually around, give or
13 take, ten years.

14 BY MR. TRISCHLER:

15 Q All right. I'm asking about specific
16 cancer types, and if you don't know, you can simply
17 tell me you don't know.

18 A Right. Again, I'm not an oncologist.
19 So no, I -- I -- the answer to your question -- the
20 last -- the answer to your last question on stomach
21 latency is I don't know.

22 Q Okay. So and if I went through the
23 nine cancer types that you mention in your report,
24 would you know the average latency period for any of
25 them?

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1 MR. NIGH: Object to form.

2 THE WITNESS: Not specifically.

3 BY MR. TRISCHLER:

4 Q We talked a little bit about the
5 Gomm -- or you talked a little bit about the Gomm
6 and Pottegard studies yesterday. And we mentioned
7 them again this morning. You're familiar with those
8 papers, right?

9 A Yes.

10 Q And I think one of the things that you
11 indicated to us was that you were critical of the
12 observations by Gomm and Pottegard in their papers
13 because the study durations too short; is that
14 correct?

15 A Yes.

16 Q Basically what you -- what you said
17 was that a study duration of -- with a study
18 duration on the order of three, four and five years,
19 it was simply too early to tell whether or not
20 nitrosamines in valsartan-containing medications
21 might have an increased risk of cancer, right? You
22 need more time?

23 A Well, for a population-based study, it
24 is short. But that doesn't mean that, you know, in
25 some patients, a shorter onset of cancer cannot

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1 occur. But when I'm looking at a -- obviously, this
2 was a population study, the ones you're mentioning.
3 And for a population study that median of
4 three years is short.

5 Q I wasn't asking you about whether
6 there's any particular individual that might have a
7 shorter latency period than another. I was asking
8 you about study design.

9 And what you told us yesterday was
10 that a study period of four or five years, which I
11 believe is the time frame in the Pottegard and Gomm
12 studies is just too short, and it's too early to
13 tell whether or not nitrosamines in
14 valsartan-containing medications can cause an
15 increased risk of cancer; you need a longer period
16 of time to study that, right?

17 A Yes.

18 MR. NIGH: Object to form. Hold on.

19 Hold on. Object to form. That was asked and
20 answered.

21 BY MR. TRISCHLER:

22 Q That's what you told us yesterday,
23 right?

24 A Yes.

25 Q Okay. And so in your opinion, how

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1 long would you have to go out to find a credible
2 study that evaluates NDMA and NDEA in
3 valsartan-containing medications and whether those
4 medications lead to an increased risk of cancer?

5 MR. NIGH: Form objection.

6 THE WITNESS: Certainly, more than,
7 you know, five years.

8 BY MR. TRISCHLER:

9 Q Okay. What does that mean? Does it
10 mean six years is enough, or do you have to go to
11 like 10, 15?

12 A Well, again, you're asking me a
13 technical question. So one has to sit down, and if
14 you're looking at different types of cancer, you
15 have to factor in the -- the different latencies of
16 all the cancers that you want to study and then make
17 sure that the follow-up period that you have in your
18 study design meets those latency periods.

19 Q Okay. So are you familiar with a
20 paper by Nadler, N-a-d-l-e-r, entitled, "Estimating
21 Cancer Latency Times Using Weibull," W-e-i-b-u-l-l,
22 "Model"?

23 A Doesn't ring a bell.

24 Q Are you familiar with the Weibull
25 model?

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1 A Yes.

2 Q What is it?

3 A A Weibull model is -- I believe it's a
4 parametric statistical model.

5 Q For estimating latency periods?

6 A I -- again, that's a technical
7 statistical question, but I believe it could be.
8 It's a very general model that's used for different,
9 sort of, outcomes and -- and one -- I mean, it could
10 possibly be used for statistical modeling of latency
11 as well. Because it looks at time, and latency is a
12 time. You know, it's a function of time.

13 Q So I'll represent to you that in
14 this -- in the Nadler paper using the Weibull model
15 to estimate cancer latency times, the authors
16 concluded that the average latency period for
17 stomach cancer is 22 years. You don't have any
18 information to dispute that, right?

19 MR. NIGH: Object to form.

20 THE WITNESS: I'm not going to agree
21 right now on the latency period, which is quite
22 a complex topic, based on just one paper.

23 BY MR. TRISCHLER:

24 Q I didn't ask you to agree to it. I
25 asked you -- I made a representation to you of the

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1 average latency period in the literature. And I
2 asked if you have any basis to dispute it.

3 MR. NIGH: Object to form.

4 THE WITNESS: No, I have no basis to
5 dispute it or agree to it.

6 BY MR. TRISCHLER:

7 Q Okay. And in -- in the same paper,
8 the authors estimate the average latency period of
9 lung cancer to be 13 years. Do you have any basis
10 to dispute that?

11 MR. NIGH: Object to form.

12 THE WITNESS: Again, I can't agree or
13 dispute.

14 BY MR. NIGH:

15 Q And so if we wanted to -- if we were
16 an epidemiologist like yourself and we wanted to
17 carry out, you know, a well-designed epidemiological
18 study to evaluate whether nitrosamines in
19 valsartan-containing medications led to an increased
20 risk of stomach cancer, we'd need to carry that
21 study out for 22 years, right?

22 MR. NIGH: Object to form.

23 BY MR. TRISCHLER:

24 Q If we assume that's the correct
25 latency period?

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1 MR. NIGH: Object to form.

2 THE WITNESS: It -- it will be -- it
3 should be a study that has a very long follow
4 up. Again, I don't want to be agreeing on
5 numbers that -- that I haven't seen or from one
6 paper. But generally speaking, it needs a long
7 period of follow up.

8 BY MR. NIGH:

9 Q And so if we're going to be -- if
10 we're going to approach the question of whether
11 nitrosamines in valsartan-containing medications
12 lead to an increased risk of cancer, we're going to
13 make that determination based on the science, what
14 you're telling us is we just don't know at this
15 point because the -- we don't have enough time to
16 answer the question, right?

17 MR. NIGH: Object to form.

18 THE WITNESS: To specifically design a
19 study that looks at oral nitrosamine, it's
20 going to be a complex study. But again, my
21 report and my review was on a general causation
22 of exposure of nitrosamine -- nitrosamines and
23 cancer.

24 BY MR. TRISCHLER:

25 Q By the way, there are -- there are a

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1 few other cancer types that are at issue in this
2 litigation, breast cancer, kidney cancer, pharyngeal
3 cancer and uterine cancer.

4 In your report, you did not observe
5 any statistically significant increased risk between
6 NDMA and NDEA exposure and breast cancer, do you?

7 A Again, I don't think a statistically
8 significant increase is the right sort of portrayal.
9 I did not include any studies, whether significant
10 or not, because they did not meet -- those types
11 studies did not meet my inclusion criteria, which --

12 Q So you don't -- I'm sorry. I didn't
13 mean to interrupt you.

14 A Go ahead.

15 Q No. I thought you were finished.

16 A I -- sorry. I think I am finished.

17 Q I guess what I'm asking is you do not
18 intend to offer an opinion that NDMA exposure or
19 NDEA exposure will lead to an increased risk of
20 breast cancer, do you?

21 A No, because it's a not in my report,
22 and I did not cover -- cover this topic.

23 Q You do not intend to offer an opinion
24 that exposure to NDMA or NDEA lead to an increased
25 risk of kidney cancer, do you?

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1 A No.

2 Q You do not intend to offer an opinion
3 that exposure to NDMA or NDEA lead to an increased
4 risk of pharyngeal cancer, do you?

5 A Well, I do have -- I do have oral
6 cancers including larynx, I believe, in my report.
7 So pharyngeal, specifically no, but I do talk about
8 oral cancers, in general, including the larynx. And
9 so, again, I do make an opinion on oral cancers in
10 general. It does not specifically say pharyngeal.

11 Q Okay. But when you say "oral
12 cancers," the only one I'm aware of that arguably
13 constitute oral, at least as I understand the
14 anatomy, is esophageal?

15 A No. Oral cancers can also include the
16 mouth, the esophagus and also the pharynx and the
17 larynx. So I do have a section in my report on
18 pharynx, larynx and the esophagus, which I combine
19 into head and neck cancers.

20 Q Okay. Do you intend to offer an
21 opinion that exposure to NDMA or NDEA increase the
22 risk of uterine cancer?

23 A No.

24 THE WITNESS: Can I interject?

25 MR. TRISCHLER: Yes.

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1 THE WITNESS: Can we take a break now
2 if you have more information to cover, but if
3 you're reaching the end, maybe we can continue.
4 Either option is okay.

5 MR. TRISCHLER: Well, I'm -- I'm
6 reaching my end, but there will be another
7 examiner, at least one other examiner that I'm
8 aware of. So we can take a break.

9 THE WITNESS: No, I understand. I
10 meant just your section.

11 MR. TRISCHLER: Yeah. You won't --
12 you won't -- we can take a break whenever you
13 want. It won't mess me up, so you're in
14 control of that. So you tell me.

15 THE WITNESS: I mean, if you have
16 another 5, 10 minutes, we can go -- you know,
17 we can continue. If it's longer, I'd like to
18 take a break.

19 MR. TRISCHLER: No, I don't have
20 any -- in fact, I think -- I think I'm probably
21 finished, so I will pass the witness. If you
22 want to take a break now then, or, you know,
23 I'll leave that up to you and Daniel.

24 THE WITNESS: Sure. Can I take a
25 break, everyone?

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1 MR. NIGH: Yeah, let's take a
2 ten-minute break.

3 THE VIDEOGRAPHER: The time is now
4 9:34. This ends Media Unit Number 1. We're
5 going off the record.

6 (Whereupon, a short break was taken.)

7 THE VIDEOGRAPHER: The time is now
8 9:49 in this begins Media Unit Number 2 we're
9 back on the record.

10 EXAMINATION BY MS. KAPKE:

11 Q Good morning, Dr. Etminan. My name's
12 Kara Kapke, and I just have a few short questions.

13 You talked about how the -- one of the
14 questions you were answering was whether NDMA or
15 NDEA exposure over time increases the risk of
16 cancer. Can you quantify the duration of time that
17 you're talking about?

18 MR. NIGH: Form objection.

19 THE WITNESS: Different studies have
20 different durations. So I can't really give
21 you a specific answer.

22 I believe that -- in the range from
23 maybe three or four years up to the study --
24 the occupational study, I believe had a 35 or
25 40-year follow up, so it is a big range.

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1 BY MS. KAPKE:

2 Q So given that -- your answer, is it
3 fair to say that a person would need to take NDMA or
4 NDEA containing valsartan for at least three years
5 before they had an increased risk of cancer?

6 MR. NIGH: Object to form.

7 THE WITNESS: No, I -- I wouldn't say
8 that because, again, every -- it's a very --
9 latency to cancer is very individualized. And
10 those are median follow-ups -- you -- which
11 means that you have -- at each end -- you have
12 a lower end and a higher end. So I can't -- I
13 don't really want to make that specific sort of
14 statement.

15 BY MS. KAPKE:

16 Q What are you willing to say, to a
17 reasonable degree of scientific certainty, that is
18 the -- minimum amount of time that a person would
19 need to have taken valsartan that contained NDMA or
20 NDEA before they are subject to an increased risk of
21 cancer?

22 MR. NIGH: Form objection.

23 THE WITNESS: Again, given that I
24 looked at general causation, I can say that
25 exposure to NDMA and NDMA valsartan increases

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1 the risk of cancer over time. I don't have any
2 specific data to, sort of, give you a specific
3 number right now.

4 BY MS. KAPKE:

5 Q You would agree with me that a person
6 who took a single pill for -- you know, one -- one
7 pill of valsartan that contained NDMA or NDEA would
8 not have an increased risk of cancer, correct?

9 A One pill over what period?

10 Q One day.

11 A No.

12 Q You don't agree or you do agree with
13 that?

14 A I agree with you that taking one pill
15 of valsartan for one day does not increase the risk
16 of cancer.

17 Q What about 30 days, so 30 days' worth
18 of pills?

19 A 30 days, probably not as well.

20 Q I'm going to push it out. How about
21 90 days?

22 A Again, less likely.

23 Q Another way you -- you framed the
24 question that you are evaluating was whether
25 systemic exposure to NDMA could cause cancer.

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1 Similar type of question, but what does "systemic"
2 mean to you?

3 A Systemic means that NDMA that's
4 available in -- in the body, and it's absorbed and
5 available in the body to, you know, all the organs.
6 All the organs are subject to some level of NDMA.

7 Q And have you ever put a quantification
8 of the dose or the duration that it takes to reach
9 that systemic exposure?

10 MR. NIGH: Form objection.

11 THE WITNESS: Can you repeat the
12 question, please?

13 MS. KAPKE: Can the court reporter
14 read it back?

15 (Whereupon, the testimony was read
16 back as requested.)

17 THE WITNESS: No.

18 MS. KAPKE: Thank you very much,
19 Dr. Etminan. I'll pass the witness.

20 THE WITNESS: Thank you.

21 EXAMINATION BY MR. FOWLER:

22 Q Good day, Dr. Etminan.

23 You may have seen me briefly
24 yesterday. Let me just reintroduce myself. I'm
25 Steve Fowler with the law firm Greenberg Traurig,

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1 and we represent the Teva defendants. I've got some
2 additional questions for you.

3 But let me just start very quickly.
4 Am I correct that in -- in your research, nor in
5 your report, did you attempt to determine whether
6 the levels of NDMA and NDEA in the valsartan tablets
7 at issue here, whether that level poses an increased
8 risk of cancer?

9 MR. NIGH: Object to form.

10 THE WITNESS: Specifically looking at
11 the levels, no. I made general sort of
12 analogies based on the NDMA levels in the
13 different manufacturers with respect to the --
14 the sort of a dose response relations that I
15 found from the occupational and epi studies.

16 BY MR. FOWLER:

17 Q I see.

18 MR. FOWLER: By the way, Mr. Nigh, is
19 there any reason that you're not on camera as a
20 -- as a speaking role in this deposition?

21 MR. NIGH: We have had many of us that
22 haven't been on camera on speaking objections,
23 you know, the people that are handling the
24 depositions. So I have seen it on multiple
25 occasions from attorneys throughout this

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1 litigation. So I'm not sure why at this point
2 you're raising this issue, almost nine hours
3 into the deposition.

4 MR. FOWLER: Well, you were initially
5 yesterday, but if you're not comfortable,
6 that's -- that's fine. I'll -- I'll leave it
7 alone.

8 BY MR. FOWLER:

9 Q Dr. Etminan, let me shift gears here
10 and go back to yesterday. I think your CV was
11 marked as Exhibit 2. I'd like to -- to put your CV
12 up.

13 MR. FOWLER: I don't know, Justin, if
14 you can do that. I think it was Number 2.

15 BY MR. FOWLER:

16 Q Are you with me, sir?

17 A Yes.

18 Q Directing your attention to the top,
19 you see the date of May 2021. Is that the date that
20 you revised or updated your CV?

21 A Yes.

22 Q And when you did that, did you review
23 your entire CV for accuracy and any changes that
24 needed to be made?

25 A To the best of my ability, yes.

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1 Q And you would -- you believe
2 everything that you've stated on your CV is true and
3 accurate to the best of your knowledge?

4 A Yes.

5 Q Do you recall what changes that you
6 made or additions in May of 2021? Was it simply
7 publications, or was it something else?

8 A No. It's usually just adding new
9 publications.

10 Q Yes, sir.

11 Now, presently, according to your CV,
12 you are an associate member in neurology, department
13 of medicine; and associate member, department of
14 anesthesiology, pharmacology and therapeutics.

15 What -- what responsibilities, if any,
16 do you have in the department of neurology, for
17 example?

18 A So as an associate member, my
19 responsibilities are far fewer than my -- my own
20 department, which is ophthalmology. For -- for
21 neurology, I'm a reviewer for the journal --
22 movement disorder and epidemiology reviewer for the
23 journal "Movement Disorder" where the editor in
24 chief happens to be also in the department of
25 neurology. So that's -- that's the connection.

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1 Q And you are -- your title as associate
2 professor in the department of ophthalmology is not
3 because you had any education, training or
4 experience in ophthalmology before changing to that
5 department, correct?

6 A Correct. So the department of
7 ophthalmology has clinical faculty who are
8 ophthalmologists. Then they have -- and then they
9 have research faculty, and I'm part of the research
10 faculty.

11 Q Yes, sir.
12 And -- and prior to that, you were in
13 the department of pediatrics; is that correct?

14 A Yes. Yes.

15 Q And you are no more a pediatrician
16 than you are an ophthalmologist, right?

17 A Correct.

18 Q You simply acquire the title when you
19 are transferred from one department to another?

20 A Well, the title doesn't -- I mean,
21 title is assistant professor or associate professor,
22 and then the department changes, right? So I'm not
23 sure what you mean by "title."

24 Q Okay. Well, before, you were an
25 associate professor in the department of pediatrics

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1 at one point, the department of respiratory medicine
2 at another point, correct?

3 A Correct.

4 Q But you have no medical training in
5 either of those specialties, right?

6 A Correct.

7 Q And you call yourself -- or I've seen
8 you call yourself an adjunct position in the
9 department of pharmacology. Do you still contend
10 that's your position?

11 MR. NIGH: Form objection.

12 You can answer.

13 THE WITNESS: In the department of
14 pharmacology -- anesthesiology, pharmacology
15 and therapeutics, yes.

16 BY MR. FOWLER:

17 Q Just to be clear, my question is, do
18 you still believe that you have an adjunct position
19 in the department of pharmacology at UBC?

20 A Yes.

21 MR. NIGH: Form objection.

22 BY MR. FOWLER:

23 Q And why do you call it adjunct? Are
24 you teaching classes in the department of
25 pharmacology?

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1 A I -- I -- actually used to teach
2 classes until last year. And I have some other
3 collaborations with some of the faculty there, so
4 that's why I do have the adjunct position.

5 Q I see.

6 Let's go to the second page of your
7 CV, please. Sir, you indicate having received your
8 PharmD at Idaho State University, and you note
9 clinical pharmacology next to it. Are you with me?

10 A Yes.

11 Q The PharmD program at Iowa [sic] State
12 does not have a separate program or separate degree
13 or track for clinical pharmacology, does it?

14 A Idaho State. No. I put clinical
15 pharmacology because many don't really understand or
16 know who are non-pharmacists what a PharmD entails.
17 And so I put clinical pharmacology just to explain
18 what the degree entails, not specifically on a
19 specific clinical pharmacology program.

20 Q Right. So you're not holding yourself
21 out as having received some special PharmD degree in
22 clinical pharmacology. Those are just the words you
23 self-selected to describe your degree, correct?

24 A Correct.

25 Q And likewise -- and also, sir, you

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1 testified yesterday you started your PharmD degree
2 at University of British Columbia, but then you
3 testified that you left. You, kind of, mentioned a
4 couple of reasons.

5 One of them, you indicated the program
6 was shorter at Iowa State. You would get your
7 degree -- at Idaho State. You would get your degree
8 faster. Is that your testimony, sir?

9 A I don't recall exactly what I said
10 yesterday, but I could clarify.

11 I believe I did say that the UBC
12 pharmacy program was clinically oriented, and I
13 wanted to pursue a research career. So I -- I
14 didn't see a fit there. And possibly, it was -- it
15 was a more, perhaps, busier, if you will, stringent
16 program that I didn't think I would really benefit
17 from. So that's why I completed my degree at Idaho.

18 Q And there's not another reason that
19 you left UBC that's a nonacademic reason, sir?

20 A No.

21 Q And the Idaho State University degree
22 is four years just as UBC, correct?

23 A It was a two-year -- two years post
24 baccalaureate program.

25 Q I see.

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1 Your master's, your MSC from
2 University of Toronto, is it your contention that
3 that was specifically in clinical epidemiology, or
4 is that, again, your choice of words to describe it?

5 A It was in clinical epidemiology.

6 Q And that was the degree that was
7 specifically conferred, sir?

8 A I believe so.

9 Q And is it your contention that you
10 were in a postdoc fellowship specifically in
11 pharmacoepidemiology at McGill as opposed to a
12 postdoc fellow in pharmacy?

13 A No, it was specifically
14 pharmacoepidemiology.

15 MR. FOWLER: You can take that down.

16 Thank you.

17 BY MR. FOWLER:

18 Q Now, sir, when you conduct research
19 projects when you seek to determine what subject
20 you're going to investigate, you testified yesterday
21 that you look to various areas defined -- "emerging
22 issues," perhaps, that you wanted to investigate.
23 Is that a fair characterization?

24 A Yes.

25 Q And you mentioned media as one source

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1 as well as health regulatory agencies, right?

2 A Correct.

3 Q But you also purposefully do studies
4 with an eye towards assisting in litigation,
5 correct, sir?

6 A I -- I wouldn't say that -- that's
7 something I do systematically, no.

8 Q Doctor, have -- have you testified
9 that you have contacted lawyers in the course of
10 starting a study because you believe that that was
11 going to be useful to them in litigation?

12 MR. NIGH: Form objection.

13 THE WITNESS: There could have been
14 one occasion where I was in the process of
15 doing the same sort of study, and a lawyer may
16 have approached me at, sort of, the same
17 timing.

18 BY MR. FOWLER:

19 Q I see. And you have done that with
20 the Mirena IUD litigation?

21 A Yes.

22 Q Bear with me, sir. I apologize.

23 And you have never contacted a drug
24 company to offer any benefit of your study or your
25 expertise, only plaintiff lawyers, correct?

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1 MR. NIGH: Object to form.

2 THE WITNESS: Again, I -- I am not --
3 you're sort of portraying it as I'm contacting
4 lawyers. The Mirena situation, as I mentioned
5 to you, was a situation where I was starting to
6 question because it was in the media, and I was
7 approached, sort of, in the same time by -- by
8 -- by a lawyer.

9 With respect to approaching
10 manufacturers, no, I have not. But I know that
11 my research has been used by them in their
12 defense.

13 BY MR. FOWLER:

14 Q You have never been retained by a
15 pharmaceutical company as an expert in any matter;
16 isn't that correct?

17 A No. I -- probably because a lot of my
18 studies where I show an increase in risk with a
19 drug, you know, they -- they don't, probably, want
20 to retain me. So that's why -- that's one of the
21 reasons I believe I have not been retained.

22 Q And they have never -- well, strike
23 that.

24 You've only been retained by counsel
25 for plaintiff in litigations involving

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1 pharmaceuticals; isn't that correct?

2 A Yes.

3 Q And you withdrew from a case where you
4 were retained by plaintiffs' counsel, you said
5 yesterday it was because of the science. But isn't
6 the reason that you withdrew from Copley v. Bayer
7 was because you weren't happy with your -- with the
8 lawyer you were working with?

9 A That could have been one of the
10 reasons as well.

11 Q Sir, do you recall testifying that as
12 a consultant for plaintiffs in the Risperdal
13 litigation that you were paid approximately
14 \$200,000?

15 A I don't -- that number, I don't recall
16 that number. I'm not sure if that's an accurate
17 number.

18 Q Have you testified that your annual
19 lawyer consulting income is 20 to \$30,000 a year, at
20 least in 2017, sir?

21 A That -- I may have mentioned that as
22 an approximation, but -- but I don't really know
23 what that \$200,000 figure is coming from.

24 Q Have -- has your consulting with
25 plaintiff lawyers increased, decreased or stayed the

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1 same since 2017, sir?

2 A Since 2017, I would say it -- I would
3 say it may have increased.

4 Q And other than the matter for
5 ranitidine that you were instructed not to discuss
6 further yesterday, do you have other pending
7 litigation matters that you are involved in? I'm
8 not asking what at the moment, sir.

9 A You just want to know if I am involved
10 in other litigation?

11 Q Yes, sir.

12 A Yes.

13 Q Okay. About how many? If this is one
14 and ranitidine is two, how many others?

15 A I just have to think about it. I have
16 to count them. When you say "litigation," do you
17 mean just the -- sort of the -- the topic area or
18 how many different perhaps groups or lawyers?

19 Q What would be the best way for you to
20 describe how many other topics that you are working
21 with lawyers on presently other than the two I have
22 mentioned?

23 A I would say two other topics.

24 Q Okay. Do you have any other
25 depositions scheduled, sir?

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1 A No.

2 Q Prior to your deposition, counsel for
3 the plaintiffs provided some documents to the
4 defendants, and what I'd like to do is just mark
5 that entire set of documents as an exhibit. Then
6 there may be some that I pull out.

7 MR. FOWLER: Can we do that, Steve?
8 Can we mark that entire production as -- as the
9 next exhibit?

10 MR. HARKINS: That will be marked as
11 Exhibit 28. It may take a moment to upload.

12 MR. FOWLER: Thank you.

13 THE WITNESS: Can I take a two-minute
14 break if you don't mind?

15 MR. FOWLER: Absolutely, Doctor.
16 You're in charge. Off the record.

17 THE VIDEOGRAPHER: The time is now
18 10:12. We're going off the record.

19 (Whereupon, a short break was taken.)

20 (Whereupon, Exhibit 28 was marked for
21 Identification.)

22 THE VIDEOGRAPHER: The time is now
23 10:15. We're back on the record.

24 BY MR. FOWLER:

25 Q Doctor, I would submit that Exhibit 28

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1 is a composite exhibit of documents that were
2 provided by counsel for plaintiffs to the defense
3 counsel prior to your dep.

4 Did you have any role in deciding, for
5 example, which articles would be included in that
6 set of documents?

7 MR. NIGH: Form objection.

8 THE WITNESS: Yes. So I included
9 documents that weighted heavily in my report
10 and the opinion presented in my report. So all
11 the major studies that I relied on, my search
12 strategy are all included.

13 BY MR. FOWLER:

14 Q And where did you get copies of those
15 articles?

16 A I ascertained the articles through the
17 UBC library, electronic library.

18 Q Yes, sir.

19 MR. FOWLER: Let's mark as Exhibit 29
20 the search criteria documents, if I can refer
21 to those as such. Are you with me, Doctor? Do
22 you know what I mean?

23 (Whereupon, Exhibit 29 was marked for
24 Identification.)

25 THE WITNESS: Which exhibit is this?

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1 MR. FOWLER: It will be 29. Bear with
2 me. It's going to come up.

3 BY MR. FOWLER:

4 Q And as it's posting, Doctor, you would
5 agree that you attempted to set forth in the
6 documents we're going to look at, your quote/unquote
7 search methodology for selecting documents to review
8 for your report; is that a fair statement?

9 A Yes.

10 Q And other than the searches that we're
11 going to look at here that are described for the
12 various cancers, was there any other medical
13 database that you reviewed or other research you did
14 to select articles other than what was the product
15 of this search criteria that we're going to look at
16 here on Exhibit 29?

17 A So as I mention in my report, I also
18 looked at -- I used Google Scholar using the same
19 terminologies. And I found pertinent articles
20 through reviewing the articles that I -- I had found
21 in case they were not listed in my search.

22 MR. FOWLER: How are we doing on
23 Exhibit 29?

24 THE WITNESS: I'm looking at it.

25 THE VIDEOGRAPHER: Yes, it's up. I

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1 was just waiting for the doctor.

2 MR. FOWLER: Okay. Because I'm not
3 seeing it. There we go.

4 BY MR. FOWLER:

5 Q Okay, sir. So let's first orient
6 ourselves to this. Can we scroll to the second
7 page? Do you see we have bladder cancer there,
8 Doctor, in the next page?

9 A Yes.

10 Q And brain -- brain tumors.

11 You're not offering any opinion that
12 NDMA at the levels contained in the valsartan pills
13 caused brain tumors, are you?

14 A No, but I --

15 Q Let's go to the top the first page.

16 MR. NIGH: Hold on. Hold on. You
17 interrupted his answer. You gotta let him
18 finish.

19 MR. FOWLER: I'm sorry. He answered
20 no.

21 MR. NIGH: No. No. No. He was not
22 finished. He said, "No, but," and you just
23 spoke up. You gotta let him finish.

24 BY MR. FOWLER:

25 Q I'm sorry, Doctor. Go ahead.

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1 A Because I did a systematic review of
2 the literature of NDMA with all types of cancer, I
3 included all types of cancer in my original search.
4 And then I -- and after I looked at the evidence and
5 synthesized the evidence, then I chose, depending on
6 the amount of data that I had, which cancers to
7 include and which not to include.

8 So, again, to be thorough and
9 systematic, I did include all types of cancers in my
10 search. But depending on the type of data and
11 whether the data met my inclusion criteria, then I
12 went ahead and mentioned in the report or included
13 data for that in the report.

14 Q I see.

15 MR. FOWLER: Let's go to Page 1 of
16 Exhibit 19 -- I mean, Exhibit 29. Now -- thank
17 you.

18 BY MR. FOWLER:

19 Q What we're looking at here, Doctor,
20 and -- is this a document that you created, or is
21 it -- is it a printout, if you will, from your
22 search engine?

23 A It's a printout. It's an electronic
24 output of the search that I did.

25 Q Okay. Thank you. And what does the

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1 EXP mean?

2 A It means expanded.

3 Q And what -- what you do you understand
4 expanded to mean?

5 A So that -- that -- basically, it looks
6 at all terminologies that would be related to
7 nitrites, all different chemical -- chemicals that
8 may be tagged in the database as nitrites just to
9 be -- to make sure that nothing is missed.

10 Q So do I understand, in Line 1, that
11 your search would have included not only NDMA, but
12 any nitrosamines?

13 A Yes, because NDMA by itself does not
14 have --

15 THE COURT REPORTER: I'm sorry. Does
16 not have a what?

17 THE WITNESS: They don't have a MeSH
18 M-e-S-H, which stands for medical subject
19 heading. I believe it's -- I believe it stands
20 for medical subject heading.

21 Anyway, it's the -- it's the key
22 medical terminologies that are tagged by the
23 National Library of Medicine, PubMed. So NDMA
24 does not have a specific tag, but it's tagged
25 under "nitrosamines."

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1 So, again, to be ensuring that I'm not
2 missing anything, I started the search with
3 nitrosamine, which is the bigger umbrella term.
4 But then I restricted at the end my inclusion
5 for studies that -- specifically with NDMA.

6 MR. FOWLER: Let's go to the next
7 page.

8 BY MR. FOWLER:

9 Q So for bladder cancer, sir, as I read
10 this, again, your 120 articles that come out of --
11 at Line 8, include anything to do with nitrosamines
12 or nitrites or NDMA, right?

13 A Right. So then what I -- what I did
14 was, go through the 120 articles, which would have
15 been animal studies where they could have looked at
16 NDMA, NDEA or other nitrosamines. But then I only
17 selected those that met my inclusion criteria, which
18 is specifically looking at nitrosamines, NDMA or
19 NDEA.

20 MR. FOWLER: Next page, please.

21 BY MR. FOWLER:

22 Q So there are 120 articles you said you
23 reviewed there, correct?

24 MR. NIGH: Form objection.

25

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1 BY MR. FOWLER:

2 Q Correct, Doctor?

3 A Yes.

4 Q And same question here for the brain
5 tumors, it's your contention that you reviewed 64
6 articles looking for NDMA or NDEA?

7 A Yes.

8 MR. FOWLER: Next -- next page.

9 BY MR. FOWLER:

10 Q And for breast cancer, is it your
11 contention you reviewed the 115 articles that are on
12 line 16 looking for NDMA and NDEA?

13 A Yes.

14 MR. FOWLER: Next page.

15 BY MR. FOWLER:

16 Q You contend there are 130 articles
17 that you looked through here?

18 A Yes.

19 Q And you did this all -- let me ask it
20 differently.

21 Did you use any kind of electronic
22 search method as you're reviewing these several
23 hundred articles, sir?

24 A No. I just went through them, read
25 the title of the article, read the abstract and then

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1 decided whether they would meet my inclusion
2 criteria or not.

3 Q And with regard to your inclusion
4 criteria, you mentioned yesterday that it was
5 important to you that the -- if NDMA is mentioned,
6 that it be quantified when it's mentioned. Is that
7 an accurate statement of your testimony yesterday,
8 sir?

9 A Yes.

10 Q It was important to you that there be
11 a measure of NDMA, not just a broad reference to
12 NDMA. Does that make sense to you?

13 A Yes.

14 Q Okay.

15 MR. FOWLER: Next page, please.

16 BY MR. FOWLER:

17 Q And Doctor, of course, you -- you
18 billed for all your time reviewing these 6, 7, 800
19 articles, didn't you?

20 A It was part of my work that I bill for
21 it, yes.

22 Q And you would have reviewed all of
23 these before you put pen to paper for your report?

24 A I'm not sure. I mean, either before
25 or maybe during the time I was writing, perhaps, say

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1 the introduction of the report, but definitely prior
2 to the time where I sort of formed -- you know,
3 formulated my opinion on the different types of
4 cancer.

5 Q And is it your testimony that you
6 can't go to PubMed and put in "NDMA" and "cancer,"
7 that it's not going to give you any results? Is
8 that what you're saying?

9 MR. NIGH: Form objection.

10 THE WITNESS: It will give the
11 results, but -- but it may not give you
12 accurate results. There could be studies that
13 may not be included in that search strategy.

14 BY MR. FOWLER:

15 Q So you didn't do it?

16 MR. NIGH: Object to form.

17 THE WITNESS: No, because, again, I
18 wanted to be more thorough and do a -- do a
19 more systematic approach.

20 BY MR. FOWLER:

21 Q Okay. Okay. And when -- let's say
22 here in esophageal cancer, in those 19 articles, if
23 you came across one or two that looked good to you,
24 would you stop there, or would you look through all
25 19?

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1 A I'm not sure what you mean by "looked
2 good." So I went through the 19, and all from --
3 from the denominator of the 19 articles, whichever
4 met my inclusion criteria was reviewed.

5 Q Okay. And did you electronically
6 slide those over to some file on your computer? Did
7 you print them? What did you do with it once you
8 identified an article?

9 A I -- I tried to look at the -- or find
10 the PDF versions so I could read them, and then I
11 would -- I saved them in files under different, you
12 know, sort of cancers.

13 Q I see.
14 And what if it -- let me start that
15 again.

16 Did you have to purchase any of the
17 articles that came up?

18 A No.

19 Q If -- if, for example, your search in
20 PubMed came up with an article that required
21 purchase, did you just move on to the next article?

22 A No. I would not leave important data
23 because it could not be purchased. I would try to
24 get it through --

25 THE COURT REPORTER: Through what?

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1 Through what? You would get it -- you would
2 get it through what?

3 THE WITNESS: Interlibrary loan
4 service.

5 BY MR. FOWLER:

6 Q And, Doctor, for each article that you
7 contend met your inclusion criteria -- let's stick
8 with esophageal cancer here -- did you cite all of
9 those articles in your report?

10 A No, I only cited, again, the articles
11 that met my inclusion criteria.

12 Q Well, that was my question, sir.
13 Let's say esophageal cancer, there
14 were 9 out of the 19 that met your inclusion
15 criteria. Would you have cited all 9, or did you
16 have another cut as to what you were going to cite?

17 A No. If -- if they met the inclusion
18 criteria, I mentioned them.

19 THE COURT REPORTER: Counsel, can we
20 go off the record for one second?

21 MR. FOWLER: Certainly.

22 THE VIDEOGRAPHER: The time is now
23 10:29. We're going off the record.

24 (Whereupon, a short break was taken.)

25 THE VIDEOGRAPHER: The time is now

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1 10:29. We're back on the record.

2 BY MR. FOWLER:

3 Q Doctor, do you recall yesterday when
4 we were talking about your report and that Table 1
5 on Page 15, you testified that you determined the --
6 the level of an unmeasured confounder that would be
7 necessary to change the relative risk reported for
8 an individual cancer? Did I get that right?

9 A Yes.

10 Q And you used this E-value methodology
11 that you referred to in your report, right?

12 A Yes.

13 Q And with regard to the E-value
14 methodology, do I recall your testimony correctly
15 that the E-valued methodology can't be applied if
16 there's more than one unmeasured confounder?

17 A Yes.

18 Q And so if -- in Table 1, if there was
19 more than one unmeasured confounder amongst, let's
20 say, the Hidajat study that you pulled from, this
21 table would be moot, correct?

22 MR. NIGH: Form objection.

23 THE WITNESS: If there was a true
24 unmeasured confounder, and we talked a lot
25 about this topic yesterday, then this -- again,

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1 this method is only designed to look at one.

2 BY MR. FOWLER:

3 Q Yes, sir. And you would consider that
4 a limitation of the E-value methodology, sir?

5 A Yes.

6 Q Okay. Are you aware of other
7 limitations to using an E-value methodology?

8 A The E-value methodology, like any
9 epidemiologic tool, has -- or carries a number of
10 assumptions. So, yes, it does have some assumptions
11 built into it. But I think that overall, it is a
12 widely accepted methodology.

13 Q Okay. Thank you. I think that was an
14 answer to a different question. Let me ask my
15 question. Listen carefully, please.

16 Are you aware of any limitations to
17 using the E-value methodology, yes or no, sir?

18 MR. NIGH: Form objection.

19 THE WITNESS: What do you mean by --

20 MR. NIGH: Hold on. Hold on. Form
21 objection and argumentative.

22 You can answer.

23 THE WITNESS: Can you -- can you
24 clarify what you mean by "limitations"? One
25 limitation we just agreed on is that it only

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1 looks at -- it can only quantify one unmeasured
2 confounder.

3 BY MR. FOWLER:

4 Q Okay.

5 A What -- what -- what other
6 limitations? Can you -- if you could just elaborate
7 on that wording.

8 Q Well, that's exactly what I'm asking
9 you, sir.

10 You expressed limitations about all
11 sorts of studies yesterday, and I'm asking about
12 this methodology. You know what the term
13 "limitations" means, right, sir?

14 A Yes.

15 Q Okay. What other limitations -- and
16 if you don't know, that's fine. Are there other
17 limitations of the E-value methodology?

18 MR. NIGH: Form objection.

19 THE WITNESS: Again, one limitation is
20 what we spoke about. The other limitation is
21 that the unmeasured confounder has to satisfy a
22 couple of other sort of criteria for the -- for
23 the E-value to work, but that's just like any
24 statistical model that is -- are based on
25 assumptions.

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1 BY MR. FOWLER:

2 Q Are you aware of any articles critical
3 of applying the E-value methodology?

4 A There have been articles talking about
5 its limitations, yes.

6 Q And did you review those prior to
7 applying the E-value methodology here to make sure
8 it was a good fit?

9 A No. Because again, it is an accepted
10 methodology used despite -- I mean, limitation is
11 a -- is a very complex term. There could be
12 limitations to a methodology, but it's still -- the
13 limitations do not outweigh its strengths. And then
14 there are limitations where you should not really
15 use a specific approach.

16 In this case, there are limitations,
17 but I think that if -- the strengths of the
18 methodology outweighs its limitations. And that's
19 why it's widely used as one way to assimilate what
20 would happen to the effect size in the absence of an
21 unmeasured confounder.

22 Q And, Doctor, for each of the cancers
23 in your Table 1 where you drew the -- the -- let me
24 start that again.

25 For each of the cancers listed in

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1 Table 1 where you have attempted to apply the
2 E-value methodology, if there is an unmeasured
3 confounder for any one or all of those cancers, your
4 conclusions from Table 1 would be null and void;
5 they would be moot, correct?

6 A No. That's not what Table 1 means.

7 Q Table 1, the magnitude of hazard ratio
8 on your right-hand column is derived using the
9 E-value methodology, correct?

10 A It's the magnitude of the hazard ratio
11 of the unmeasured confounder necessary to make the
12 hazard ratio on the left null, so for the first
13 cancer, for it to go from 1.72 to 1.0.

14 Q Yes, sir. Thank you.

15 And if that stomach cancer there is a
16 second unmeasured confounder that you would not be
17 able to calculate -- strike that -- you would not be
18 able to apply the E-value methodology. I thought we
19 established that; am I right?

20 A Correct.

21 MR. NIGH: Form objection.

22 BY MR. FOWLER:

23 Q Okay.

24 THE COURT REPORTER: Counsel, I'm
25 sorry. Can we just go off the record for one

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1 more second?

2 MR. FOWLER: Sure.

3 THE VIDEOGRAPHER: The time is now
4 10:36. This ends Media Unit Number 2. We're
5 going off the record.

6 (Whereupon, a short break was taken.)

7 THE VIDEOGRAPHER: The time is now
8 10:37. This begins Media Unit Number 3. We're
9 back on the record.

10 BY MR. FOWLER:

11 Q Doctor, from the Hidajat study on the
12 rubber workers, you agree that they were exposed to
13 multiple carcinogens, correct?

14 MR. NIGH: Object to form. I think
15 that's the 21st time that question has been
16 asked.

17 MR. FOWLER: Well, it was just a
18 foundation because I was shifting gears, sir.

19 BY MR. FOWLER:

20 Q Right, Doctor?

21 A Correct.

22 Q And you have not and cannot draw any
23 conclusion that any of the workers who expired in
24 that study died from NDMA cancer, NDMA-induced
25 cancer, correct?

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1 A Can you repeat the question, please?

2 Q You cannot tell -- and the authors of
3 this study made no -- reached no conclusion that any
4 of the workers who died during this study period
5 died as a result of NDMA-induced cancer; isn't that
6 correct?

7 A Well, the study actually showed
8 elevated risks of death secondary to high NDMA use
9 versus low NDMA use in the different types of
10 cancer. That's what the study actually set out to
11 do. I'm -- I'm missing your question. I'm sorry.

12 Q Okay. I'll just withdraw that and
13 move on.

14 Sir, you testified yesterday that the
15 mechanism of cancer with exogenous exposure may take
16 longer follow up than for endogenous exposure. Do
17 you recall that testimony?

18 A I do. If I could clarify.

19 Q I really -- I only had that one
20 question, if you recall testifying.

21 And so my follow-up to that is, you
22 further testified that you believe it takes longer
23 because you have to take it longer. It has to be
24 digested and absorbed. Do you recall saying that?

25 A Well, now that I think about it, I'd

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1 like to clarify that endogenous -- endogenous NDMA
2 or nitrosamines or NDMA, nitroso compounds in
3 general, I mean, they are already in the body. But
4 they have -- they have been -- they got into the
5 body from the outside, from the environment, from
6 our food.

7 So now that I think about it again, I
8 believe both exogenous and endogenous may take time
9 for -- you know, for their effect to take place with
10 respect to cancer.

11 I think the reason I said what I said
12 yesterday is it was in reference to the Jakszyn
13 study because the Jakszyn study had data on
14 endogenous nitrosamines, which means that they had
15 already been there and measured in that population.

16 But they had to get there somehow in
17 the body, and that's probably through, again,
18 outside. So a lot of endogenous NDMA could
19 initially be exogenous, and it's just a matter of
20 when you're measuring, you know. When you're
21 measuring NDMA, you're measuring somebody's blood,
22 and there is NDMA in there, that would be
23 endogenous. But they have to be taking it from the
24 outside to -- for that NDMA to get into the body.

25 So I'm not sure if I answered your

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1 question, but I just wanted to clarify on endogenous
2 versus exogenous.

3 Q Thank you, Doctor.

4 And if I understand what you just
5 said, you believe that -- that endogenous levels of
6 NDMA at some point started from the outside? Is
7 that what you're saying?

8 A I think so, because as we've
9 discussed, they -- NDMA is in the environment, and
10 it gets into our body eventually. So I'm not aware
11 of any mechanisms that the body itself creates
12 endogenous NDMA. It has to be brought into our body
13 from -- exogenously, if you will.

14 Q You're not aware because you're not a
15 toxicologist, correct?

16 A No.

17 Q This is completely outside your field
18 of education, training or experience to be
19 commenting on endogenous NDMA, correct, sir?

20 MR. NIGH: Object to form. He's been
21 asked numerous questions about this.

22 You can -- you can answer.

23 THE WITNESS: I -- I -- again, I was
24 asked about endogenous NDMA with respect -- in
25 an epidemiological studies context. I did not

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1 opine, nor did I -- was I asked, I believe, to
2 opine about, you know, toxicologic --
3 toxicological aspects of endogenous NDMA. It
4 was just in the context of that one study --
5 study that we discussed yesterday.

6 BY MR. FOWLER:

7 Q Okay. Thank you.

8 And, Doctor, am I correct that you are
9 unaware of the mechanism by which NDMA can be a
10 carcinogenic substance in animals, for example?

11 A Well, from the literature that I have
12 read and I have included in my report, it's through
13 genotoxic mechanisms and potentially through other
14 mechanisms that would qualify as a promoter for
15 cancer.

16 Q You are not -- you have never
17 published on quote/unquote cancer promoters, have
18 you, sir?

19 THE COURT REPORTER: Cancer what?

20 MR. FOWLER: Promoters.

21 BY MR. FOWLER:

22 Q Right?

23 A No, that's not my field. What I
24 was -- what I was trying to say is that for the
25 biological plausibility section of my report and my

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1 readings, I have reviewed some basic science cancer
2 studies to form my opinion about the mechanism of
3 NDMA cancer.

4 Q And you do not have an opinion whether
5 any of the NDMA or NDEA contained in valsartan
6 products ever leaves the liver, correct?

7 MR. NIGH: Form objection.

8 THE WITNESS: I cannot -- I don't have
9 an opinion on that.

10 BY MR. FOWLER:

11 Q And if it doesn't leave -- did you
12 consider what body systems -- what tissue systems
13 NDMA that is ingested in -- with an oral -- orally
14 ingested in tablet form, did you make any attempt to
15 consider what parts of the body that oral ingestion
16 may reach at the level of exposure in the pill?

17 A I believe that's a --

18 MR. NIGH: Hold on. Hold on. Hold
19 on. Hold on.

20 Are you done with the question?

21 MR. FOWLER: I am.

22 MR. NIGH: Okay. Form objection.

23 You can answer, Doctor.

24 THE WITNESS: I believe that's a more
25 of a basic pharmacology toxicology question

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1 you're asking me. That's not my field, and I
2 did not look at that.

3 BY MR. FOWLER:

4 Q Does -- does exposure to a chemical
5 that -- that is being studied, does exposure affect
6 the biologic plausibility in any attempt to evaluate
7 the biologic plausibility, sir?

8 MR. NIGH: Form objection.

9 THE WITNESS: Can you clarify?

10 BY MR. FOWLER:

11 Q Sure. Does the method of exposure
12 affect the analysis of biologic plausibility when
13 assessing if exposure can lead to cancer?

14 MR. NIGH: Form objection.

15 THE WITNESS: Yes, it could.

16 BY MR. FOWLER:

17 Q Doctor, the Hidajat study used a
18 sub-distribution hazard analysis; is that your
19 recollection?

20 A That's right.

21 Q And given that it was over the course
22 of 49 years of observation, the 94.1 percent of the
23 study had died, would you agree it's very difficult
24 to determine cause of death?

25 A I disagree because this was one of the

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1 few papers that actually -- what the
2 sub-distribution hazard that you explained does is
3 actually controlled -- it calculates the hazard of
4 death. It controls the hazard of death due to
5 cancer from death due to other causes. And this was
6 rightfully done -- because of the very long follow
7 up, it's likely that these men could die of other
8 causes.

9 And if you don't take that into
10 account, you may actually see a protective effect
11 from any exposure, because people are not surviving
12 long enough to get cancer. And so the
13 sub-distribution hazard -- it's called
14 sub-distribution hazard because it comes from a sort
15 of a -- I don't want to say different, but a more
16 sophisticated model that takes into account death
17 due to other causes.

18 Q Do you know how to calculate a
19 sub-distribution hazard ratio?

20 A I'm familiar with the methodology, and
21 the modeling that -- they have the equation in their
22 paper actually.

23 Q But you've never done it?

24 A I don't think I have done it --

25 MR. NIGH: Hold on. Hold on.

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1 Form objection. I can't tell, "you've
2 never done it," calculated whenever or from
3 that study. Form objection.

4 MR. FOWLER: Thank you for clarifying,
5 Counsel.

6 BY MR. FOWLER:

7 Q Dr. Etminan, you have never, yourself,
8 made any such calculation of a sub-distribution
9 hazard ratio at any time, correct?

10 A No, because I haven't done studies
11 that have such a long follow up. So I have not done
12 it myself, but I'm familiar with the methodology.

13 Q Okay. Sir, yesterday, we talked -- or
14 you talked a good bit about the relative risk
15 calculations and your opinions with regard to when
16 there is a wide confidence interval. Do you recall
17 those -- that testimony?

18 A Yes.

19 Q And you -- you said that it was a wide
20 confidence interval because of a small sample size?
21 Is that -- is that what you believe?

22 A Well, sometimes it is a sample size,
23 but it's actually more a function of number of cases
24 or cancer cases, which sometimes can be a function
25 of sample size, sometimes not. So if I want to be

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1 more precise, I would say that the width of the
2 confidence interval is -- is one of the -- one of
3 the variables that affects the precision or the
4 width of the confidence interval or the number of
5 events or cases, which -- which could be related to
6 sample size.

7 Q And you agree, Doctor, that high
8 variability can also affect the confidence interval?

9 A That is also one of the other
10 parameters that can affect the confidence interval,
11 yes.

12 Q And, Doctor, when you're talking about
13 sample size, let me just give you a hypothetical.
14 If there were 5,000 patients in a -- in a cohort
15 study and somebody is studying the number of
16 pancreatic cancers, for example, let's say there's
17 14, do you -- is it your contention that the 14 is
18 the sample size or the 5,000 cohort members?

19 A Again, to be more precise, in many
20 cases, sample size is a function of the number of
21 cases as well. So I mean, usually if you have a
22 larger sample size for many conditions, let's say,
23 heart attacks, the more people you follow up, the
24 more people are going to have heart attacks.

25 So in this situation, sample size and

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1 number of events are sort of directly proportional.
2 But there are situations such as cancer where you
3 have a large sample size, but you still have a small
4 number of events. So what affects the precision of
5 confidence interval is mostly -- it can be a sample
6 size issue, but it's mostly directly related to the
7 number of events or cases.

8 Q Doctor, you mentioned several times
9 yesterday that the P value, according to the ASA,
10 has -- has lost importance; is that a fair
11 characterization?

12 A Well, it's still being used and
13 accepted by many journals, but what I -- I believe I
14 said was that the ASA has warned on the
15 interpretation of what the P value is and what it is
16 not.

17 Q Yes, sir. And the P value is simply
18 the probability that results such as those actually
19 observed in the study could arise under the null
20 hypothesis? That's what a P value is, correct?

21 A Yes.

22 Q And what is the null hypothesis in the
23 Hidajat study, Doctor?

24 MR. NIGH: Form objection.

25 THE WITNESS: The null hypothesis --

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1 hypothesis would be that there is no risk of
2 NDMA with cancer deaths.

3 BY MR. FOWLER:

4 Q Did you operate under a null
5 hypothesis in your research and report drafting in
6 this case, sir?

7 MR. NIGH: Form objection.

8 THE WITNESS: No, because null
9 hypotheses are done when you actually want to
10 do an -- a true experiment. When you're
11 looking at observational studies you don't --
12 you don't have a -- I mean, you don't start
13 with a null hypothesis. You -- you would form
14 a hypothesis, but null hypotheses are mostly
15 related to when you're designing your
16 randomized trial and you want to calculate your
17 sample size. And you have --

18 THE COURT REPORTER: I'm sorry, what?
19 I'm sorry. Can you repeat the end of your
20 answer?

21 THE WITNESS: What part of it did you
22 want me to repeat?

23 THE COURT REPORTER: The hypotheses
24 are mostly related to designing your randomized
25 trial and you want to calculate your sample

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1 size. And you have...

2 THE WITNESS: Yeah. So a null
3 hypothesis is mainly used in a true -- in a
4 randomized trial or a true experiment. When
5 you want to calculate your power of the study,
6 the null hypothesis is important. But for
7 observational studies where I'm reviewing
8 literature on a specific topic, I don't really
9 see why a null hypothesis would be beneficial.

10 BY MR. FOWLER:

11 Q Doctor, when there are studies that
12 are based on hospitalized patients, you agree that
13 there is a bias to the -- the self-reporting from
14 those patients? Do you understand the question?

15 MR. NIGH: Form objection.

16 THE WITNESS: I understand your
17 question, but you have to be very specific,
18 because self -- I mean, if it's a
19 hospital-based study and both cases and
20 controls are in the hospital, then you wouldn't
21 have a self-reporting limitation.

22 So it -- it's -- you have to have the
23 very specifics of the study, and then you have
24 to show exactly where a limitation of bias
25 would affect the outcome. I mean, I don't want

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1 to make generalizations on a hospital-based
2 study.

3 BY MR. FOWLER:

4 Q Sure. Let me try it this way: For a
5 lung cancer patient who's being presented with a
6 survey to complete which may help them understand
7 the cause of their lung cancer, do you believe that
8 that creates a reporting bias from the patient?

9 MR. NIGH: Form objection.

10 THE WITNESS: The reporting bias would
11 only occur if the patient also believed that
12 the -- and these questionnaires are very long.
13 It's not about, you know, did you take this or
14 that. They -- they covered a whole host of
15 different items. So unless a patient knows
16 that a specific item is linked to the -- to
17 their lung cancer, then no, I won't -- I
18 wouldn't see any sort of a differential bias in
19 that situation in terms of the cases and many
20 controls.

21 BY MR. FOWLER:

22 Q Okay.

23 MR. FOWLER: I'm going to mark
24 Exhibit 30. It's an article applying the
25 Bradford Hill criteria in the 21st century.

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1 Steve, can you load that up?

2 (Whereupon, Exhibit 30 was marked for
3 Identification.)

4 THE WITNESS: Do you mind if I take a
5 break after your question with the article?

6 MR. FOWLER: Yes, this will be -- my
7 last series of questions will be on this
8 article and I'm done, sir. Can you make it
9 10 minutes?

10 THE WITNESS: Absolutely.

11 MR. FOWLER: Thank you.

12 MR. HARKINS: Introduced as
13 Exhibit 30, if we can screen share.

14 THE WITNESS: Let me just -- I'm
15 having trouble.

16 BY MR. FOWLER:

17 Q There it is. Can you see that now?

18 A Yes.

19 Q Okay. Thank you. Do you recognize --
20 have you seen this article before, Doctor?

21 A I may have. I'm not sure.

22 Q Do you agree or disagree that when
23 doing an analysis using the Bradford Hill criteria,
24 that it is appropriate to look to scientific
25 articles in addition to epidemiologic articles when

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1 assessing any of these criteria?

2 A What do you mean -- what do you mean
3 between scientific article versus epidemiological
4 articles?

5 Q Fair point, sir.

6 Do you agree that studies -- molecular
7 studies, toxicology studies are appropriate to
8 consider along with epidemiology studies when
9 analyzing something under the Bradford Hill
10 criteria?

11 MR. NIGH: Form objection.

12 THE WITNESS: I believe it depends on
13 the question you're trying to ask. If your
14 question is a general causation question and
15 part of the Bradford Hill criteria requires a
16 biologic plausibility, which usually requires a
17 sort of mechanistic explanation, from animal
18 studies. Then I don't think one would need --
19 for this specific question, need to go any
20 further examining, you know, other than that
21 mechanistic part of the Bradford Hill that
22 requires some evidence of a mechanism from
23 animal studies.

24 Beyond that, I don't think this
25 question warrants further review of, you know,

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1 complicated toxicological studies because,
2 again, it -- the question doesn't really mean
3 that. The question is on general causation.
4 So I would -- I would maybe shorten my answer,
5 if you will. It depends on the question.

6 For the question that I answered, I
7 don't believe that those types of studies were
8 necessary.

9 BY MR. FOWLER:

10 Q Thank you.

11 Let me direct your attention to
12 criteria five, biologic gradient.

13 MR. FOWLER: I think it's on like the
14 fifth or sixth page, please. There are no page
15 numbers on mine.

16 BY MR. FOWLER:

17 Q Okay, sir. Do you see that Hill,
18 referring to Sir Bradford Hill, wrote that, "If the
19 dose response is seen, it is more likely that an
20 association is causal."

21 Do you see that, sir?

22 A Yes.

23 Q And if you look about five lines down
24 you see, "However, Hill acknowledged that the more
25 complex dose-response relationships may exist, and

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1 modern studies have confirmed that a monotonic dose
2 response curve is an overly simplistic
3 representation of most causal relationships."

4 Do you agree with that, sir?

5 MR. NIGH: Form objection. Agree that
6 that's what it says or agree with that
7 statement?

8 MR. FOWLER: Thank you.

9 BY MR. FOWLER:

10 Q Do you agree with that statement?

11 A Again, I think Hill is presenting a
12 very general idea, and I -- it could be true for
13 some instances and perhaps not for others.

14 Q Do you believe that -- strike that.
15 Let me just look a little bit further
16 down.

17 You see after Footnote 9, "Integration
18 of advanced statistical capabilities, data modeling
19 techniques and knowledge from understanding of
20 biomolecular interactions have resulted in the
21 descriptions of more defined dose response curves
22 capable of showing molecular effects at very low
23 levels of exposure."

24 Do you agree that that -- that
25 understanding the molecular effects at very low

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1 levels of exposure for your analysis here would be
2 important?

3 MR. NIGH: Form objection.

4 THE WITNESS: Again, these are not
5 from Bradford Hill himself. I believe these
6 are the opinions of the authors, correct?

7 BY MR. FOWLER:

8 Q I'm asking if you agree with that --
9 that statement, sir.

10 A Well, I want to -- I mean, I think
11 it's important to sort of establish that these
12 are -- what we have here on this screen and I'm
13 reading, are the opinions of the authors of this
14 paper.

15 MR. NIGH: Doctor, you have a right --
16 you have a right to look at this document. You
17 can upload it, remember, and look at it.
18 That's why it's put into chat.

19 THE WITNESS: Okay.

20 BY MR. FOWLER:

21 Q My question, Doctor, just so you keep
22 it top of mind -- of course, you can look at
23 whatever you like.

24 Do you agree that it would have been
25 important for forming your opinions in this case to

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1 understand the molecular effects at very low level
2 of exposure to NDMA and NDEA?

3 MR. NIGH: Form objection.

4 THE WITNESS: No. I don't agree
5 because, again, I was looking at a general
6 causation question of exposure of NDMA over a
7 long period. You know, it could have been
8 three years, five years, up to 40 years. That
9 was my question.

10 And what these authors are -- are, I
11 believe, arguing, does not -- does not talk
12 about any specific type of question, does not
13 talk about the -- you know, the type of
14 exposure, the -- the risk of cancer, the type
15 of risk of cancer or the -- or the follow-up
16 involved.

17 So for my specific question that I set
18 out to answer, I don't believe any -- I mean,
19 if there -- if there was any specific modeling
20 data, I would have looked at it. But I don't
21 believe that would negate looking at studies
22 that looked at -- at those responses.

23 And by the way, the Hidajat studies
24 did quite a sophisticated dose response
25 analysis. So, again, I -- I don't quite

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1 understand what these authors are -- are
2 referring to when they're talking about
3 modeling, because statistical dosing modeling
4 was done in some of the studies that I
5 included.

6 BY MR. FOWLER:

7 Q I want to show you the paragraph that
8 starts, "Biological gradient." It's just down below
9 this box.

10 Doctor, "Biological gradient is an
11 example of how data integration can complicate
12 causal inference." Do you agree with that
13 description of the Bradford Hill criteria,
14 biologic -- biological gradient?

15 A Yes.

16 Q And if you look three lines -- strike
17 that.

18 The next sentence, "New tools and
19 technical capabilities have allowed researchers to
20 characterize a variety of low level molecular end
21 points that may not lead to disease or observable
22 outcomes on a larger scale."

23 Did I read that correctly, Doctor?

24 A Yes, I'm just rereading it.

25 Q Yes, sir.

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1 And it says further down, "Thus
2 molecular changes within the no observable adverse
3 effect level may not contribute to disease and are
4 more indicative of a threshold dose."

5 Doctor, with that backdrop, did you
6 make any attempt to determine whether there is a no
7 observable effects level for low doses of NDMA or
8 NDEA?

9 MR. NIGH: Form objection.

10 THE WITNESS: Again, that wasn't the
11 question that I set out to answer. The
12 question that I set out to answer was -- was
13 exposure to NDMA over a long period of time,
14 high dose versus low dose, has a differential
15 risk of cancer. What they're talking about
16 here are -- again, they don't really specify
17 the type of studies, the type of exposure. I
18 think they're making very -- very general
19 statements on the very large sort of scope of
20 topics.

21 BY MR. FOWLER:

22 Q And do you believe, Doctor, that the
23 biological gradient of the Bradford Hill criteria
24 can be satisfied when evaluating NDMA and NDEA
25 without an understanding of any threshold dose

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1 level?

2 MR. NIGH: Form objection.

3 THE WITNESS: I think threshold dose
4 levels are a very technical, specific question
5 with respect to NDMA and cancer. The more
6 general question that's sort of the umbrella
7 question that I was set up to look at was,
8 generally speaking, does exposure to NDMA over
9 a long period cause cancer. And I don't
10 believe that you need -- I mean, they were --
11 statistical modeling was used in the studies.
12 But I don't -- I don't think you specifically
13 need sophisticated tools or modelings to set
14 out the question that I -- that I wanted to
15 answer.

16 BY MR. FOWLER:

17 Q Well, Doctor, looking at the first
18 part of this criteria five, it states that
19 Sir Bradford Hill -- it says, "However, Hill
20 acknowledged that more complex dose relationships
21 may exist."

22 Did you consider that when trying to
23 evaluate the biological gradient for NDMA, sir?

24 MR. NIGH: Form objection.

25 THE WITNESS: Again, I did not have,

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1 you know, data on NDMA gradient or doses.
2 My -- my question was to look at the literature
3 and answer the question whether long-term
4 exposure to NDMA causes cancer. Again, I go
5 back to what I mentioned a few minutes --
6 seconds ago.

7 BY MR. FOWLER:

8 Q Yes, sir.

9 A Your -- your question I believe is
10 looking at a more specific type of a question.

11 For a general causation question, I do
12 not believe that -- and, again, with Bradford Hill's
13 statement here, which is very general, I do not
14 believe that for the question that I set out to do,
15 I needed that information that you mentioned.

16 Q Thank you.

17 MR. FOWLER: I have nothing further,
18 sir. I think we have left some time remaining
19 for any follow-up questions. Thank you for
20 your time over these two days. I appreciate
21 it.

22 THE WITNESS: Thank you.

23 MR. NIGH: Do we have anybody else
24 that's asking questions on the defense side?
25 Steven, do you know?

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1 MR. FOWLER: No, sir. I don't believe
2 we do.

3 MR. NIGH: Okay. Can we get a -- are
4 we on the record, or can we go off the record?

5 THE VIDEOGRAPHER: Yes. The time is
6 now 11:09. We're going off the record.

7 (Whereupon, a short break was taken.)

8 THE VIDEOGRAPHER: The time is now
9 11:27. We're back on the record.

10 MR. NIGH: Steven, this is -- in
11 response to your question earlier about not
12 being on camera, I didn't want to be short with
13 you, and I did want to give you a reason. My
14 daughter has been -- was diagnosed with COVID
15 about a week and a half ago. I think that's
16 the timing. And so, frankly, I have had to
17 do -- and defend the deposition remotely. So I
18 don't have the same sort of bandwidth that I
19 have in my office. And with that, we have had
20 some storms that have rolled through both
21 yesterday and today. And when I'm on -- not on
22 video, but just speaking, then it doesn't have
23 as much breakup.

24 So I think right now, it's probably
25 okay. The weather is a little bit better

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1 outside, but I figured I'd give you that
2 explanation since you asked. And I know that
3 we have had, you know, multiple other past
4 depositions where the one making objections has
5 not appeared on camera.

6 MR. FOWLER: Thank you. And best
7 wishes for you daughter's recovery. I'm sorry
8 to hear that.

9 MR. NIGH: Yes, thank you.

10 At this time, we do -- we're not going
11 to ask any questions, and so I'd like to thank
12 Dr. Etminan for his time. And I think that
13 this time, you're free to go. Thank you.

14 THE VIDEOGRAPHER: The time is now
15 11:27. This ends today's deposition. Thank
16 you. Thank you all.

17 THE COURT REPORTER: Counsel, does
18 anybody want copies?

19 MR. NIGH: We will want one copy. It
20 can come to me on the plaintiff's side, I don't
21 know if you have my information already -- and
22 then we do want a -- we do want to read the
23 transcript --

24 THE COURT REPORTER: Sure.

25 Any other counsel?

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1 MR. GALLAGHER: Duane Morris would
2 like a copy. I think we're already set up to
3 get one, but just in case.

4 MR. HARKINS: Same for
5 Greenberg Traurig. If you don't have an order
6 for us, we certainly want a copy.

7 MS. KAPKE: Jamie, this is Kara from
8 CVS and Rite Aid. I'll take a copy, just
9 regular delivery, etrans.

10 MR. TRISCHLER: This is Clem Trischler
11 from Mylan. I think we have -- we should have
12 a standing order for all depositions, so we
13 would want that. But if we don't, or if you
14 don't have that, we do want a copy.

15 THE COURT REPORTER: Counsel, anyone
16 else?

17 MR. SHAH: This is Nakul Shah for
18 Hetero Drugs and Hetero Labs. We would like a
19 final version of the transcript as well.

20 THE COURT REPORTER: Okay. Anything
21 else, counsel?

22 (Whereupon, the deposition concluded
23 at 11:27 a.m.)
24
25

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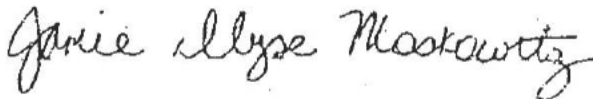
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C E R T I F I C A T E

I, Jamie I. Moskowitz, a Shorthand
(Stenotype) Reporter and Notary Public, do hereby
certify that the foregoing Deposition, of the
witness, MAHYAR ETMINAN, taken at the time and place
aforesaid, is a true and correct transcription of my
shorthand notes.

I further certify that I am neither
counsel for nor related to any party to said action,
nor in any way interested in the result or outcome
thereof.

IN WITNESS WHEREOF, I have hereunto set
my hand this 2nd day of September, 2021.



Jamie Ilyse Moskowitz

License No. XI01658

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1 Daniel A. Nigh, Esq.

2 dnigh@levinlaw.com

3 September 2, 2021.

4 RE: In Re: Valsartan, Losartan, Et Al v.

5 8/25/2021, Mahyar Etminan (#4772413)

6 The above-referenced transcript is available for
7 review.

8 Within the applicable timeframe, the witness should
9 read the testimony to verify its accuracy. If there are
10 any changes, the witness should note those with the
11 reason, on the attached Errata Sheet.

12 The witness should sign the Acknowledgment of
13 Deponent and Errata and return to the deposing attorney.
14 Copies should be sent to all counsel, and to Veritext at
15 cs-ny@veritext.com.

16
17 Return completed errata within 30 days from
18 receipt of testimony.

19 If the witness fails to do so within the time
20 allotted, the transcript may be used as if signed.

21
22 Yours,

23 Veritext Legal Solutions
24
25

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1 In Re: Valsartan, Losartan, Et Al v.

2 Mahyar Etminan (#4772413)

3 E R R A T A S H E E T

4 PAGE_____ LINE_____ CHANGE_____

5 _____

6 REASON_____

7 PAGE_____ LINE_____ CHANGE_____

8 _____

9 REASON_____

10 PAGE_____ LINE_____ CHANGE_____

11 _____

12 REASON_____

13 PAGE_____ LINE_____ CHANGE_____

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16 PAGE_____ LINE_____ CHANGE_____

17 _____

18 REASON_____

19 PAGE_____ LINE_____ CHANGE_____

20 _____

21 REASON_____

22 _____

23 _____

24 Mahyar Etminan

Date

25

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1 In Re: Valsartan, Losartan, Et Al v.

2 Mahyar Etminan (#4772413)

3 ACKNOWLEDGEMENT OF DEPONENT

4 I, Mahyar Etminan, do hereby declare that I
5 have read the foregoing transcript, I have made any
6 corrections, additions, or changes I deemed necessary as
7 noted above to be appended hereto, and that the same is
8 a true, correct and complete transcript of the testimony
9 given by me.

10
11 _____
12 Mahyar Etminan

_____ Date

13 *If notary is required

14 SUBSCRIBED AND SWORN TO BEFORE ME THIS

15 _____ DAY OF _____, 20____.

16
17
18 _____
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